Exhibit 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	12/15/2008 - 02/02/2009
	FEI NUMBER ~~1937079~~ 3007259359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. David A. Van Vliet, Interim President and Interim Chief Executive Officer

FIRM NAME	STREET ADDRESS
KV Pharmaceutical Co Westport	2280 Schuetz Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-3411	Human Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Observations cover inspections at the following firms inspected from 15Dec2008 - 02Feb2009

- KV Pharmaceuticals, Inc., 2503 South Hanley Road, St. Louis, MO 63144-FEI#1940015
- KV Pharmaceuticals, Inc., (Westport), 2303 Schuetz Road, St. Louis, MO 63146-FEI#1937079
- KV Pharmaceuticals, Inc., (R&D Lab Metro II), 10858 Metro Court, Maryland Heights, MO 63043-FEI#3002946714
- KV Pharmaceuticals, Inc., (Earth City I), 13622 Lakefront Dr., Earth City, MO 63045-FEI#3003266206
- KV Pharmaceuticals, Inc., (Earth City IV), One Corporate Woods Dr., Bridgeton, MO 63044-FEI#3004839832
- KV Pharmaceuticals, Inc., (Controlled Release), 8050 Litzinger Road, St. Louis, MO 63144-FEI#1922566
- KV Pharmaceuticals, Inc., 2258 Schuetz Road, Maryland Heights, MO 63043-No FEI
- KV Pharmaceuticals, Inc., 2280 Schuetz Road, St. Louis, MO 63146-FEI#3007259359
- KV Pharmaceuticals, Inc., 10876 Metro Court, Maryland Heights, MO 63043-No FEI
- KV Pharmaceuticals, Inc., 13910/13912 St. Charles Rock Road, Bridgeton, MO 63044-FEI#1922566

QUALITY SYSTEM

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, the Quality Control/Quality Assurance (QC/QA) functions have failed as evidenced by the following examples

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	Gwyn S Dickinson, Investigator Michele Perry Williams, Investigator Regina T. Brown, Investigator Kara L. Roden, Investigator Eric C. Nielsen, Investigator Patrick L. Wisor, Investigator Warren J. Lopicka, Investigator Jennifer Cahill, Investigator Joseph R. Lambert, Investigator Matthew J. Morrison, Investigator Tara L. King, Investigator	02/02/2009

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and the remaining observations cited on the FDA 483.

For example,

a. After dissolution failures occurred with Metoprolol Succinate 25 mg ER Tablets manufactured with ER pellet lots with below target assay values, several lots of the ER pellets (#'s 96671, 96856, 96857, 96858, 96859, 96860), with assay values below the target were blended off with ER pellet lots with assay values at or above the target value. There is no formal documentation or justification for the blend-off process. This blending off of sub par product was conducted in approximately [redacted] lots of bulk tablets from September until November 2008. This was performed at the instruction of upper management and acceptance by Quality Assurance.

b. After dissolution problems were encountered with Metoprolol ER pellets due to high acetic acid values [redacted] in [redacted] a decision was made by upper management with no formal documentation or justification, to blend off lots of [redacted] which assayed above [redacted] with lots assayed at or below [redacted]. Lot #121415 of [redacted] had an acetic acid value of approximately [redacted] and was used with lot# 122572 [redacted] in at least [redacted] lots of ER pellets (#'s 98950-98954 and 101203-101214) in November of 2008.

c. The quality control unit has failed to implement adequate corrective and preventative action into the hundreds of complaints of leaking capsules received on PrimaCare One, Prenatal Multivitamin/Mineral Capsules. The firm continued distribution of this product despite continued complaints of leaking capsules as evidenced by the following. The investigation is ongoing and product is currently being reformulated.

- 2007 complaint statistics; over 350 complaints of leaking capsules for PrimaCare One, with 26 documented adverse event reports (ADEs);
- Correspondence from the manufacturing firm dated 02Jan2008 in which an "improvement plan" is addressed for the PrimaCare One manufacturing process; and by
- 2008 complaint statistics; over 630 complaints of leaking capsules with 21 documented ADEs.

d. Rework by re-screening due to unacceptable particle size was performed in August 2007, without change control, QA approval and validation, on IR pellets lot# 87843 (C-664). This pellet lot was used during the remainder of 2007 and early 2008 in the manufacture of [redacted] Metoprolol Succinate 100 mg/200 mg tablet batches which were subsequently released. The batches included lot #'s [redacted] Further, a pre-approval supplement was not pursued for this rework process nor was this rework process submitted in the Annual Report dated 05Jul2008. Notes from an upper management meeting indicate the re-screened product cannot be used for commercial sale until the pre-approval supplement is approved.

e. The quality unit did not effectively review the packaging batch record prior to the release of Oxycodone 15mg Tablets

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lot # 90330 to the market. This batch was packaged using bulk tablet lot # 83391 which had been rejected when it failed the finished product specifications for assay. Awareness of the release of the failed batch was realized when the warehouse could not locate the failed lot of product for destruction on 29Jun2008. The packaging batch record for lot # 90330 referenced the two different bulk tablet batches of Oxycodone 15 mg, lots #'s 91391 and 83391. However, only lot # 83391 was used. Additionally, the packaging batch record contained the incorrect COA (for lot 91391); it did not contain the COA for lot # 83391.

OBSERVATION 2

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, for Metoprolol Succinate Extended Release (ER) tablets, Hydromorphone Tablets, Morphine Sulfate ER Tablets, and prescription nutritional supplements, the process steps executed to accomplish manufacture have historically resulted in variable products of unreliable quality, different than the product results obtained from the designed, validated process studies.

Metoprolol Succinate ER Tablets

a. It does not appear the Metoprolol Succinate ER Tablets product line (25 mg, 50 mg, 100 mg, 200 mg) was developed in a scientifically sound manner with appropriate specifications and process controls. All strengths have historically resulted in drug product of variable quality when, the designed processes are executed as evidenced by the high numbers of batch rejects, in-process rejects, out-of-specification (OOS) test results and non-conformance reports (NCRs) at all manufacturing stages.

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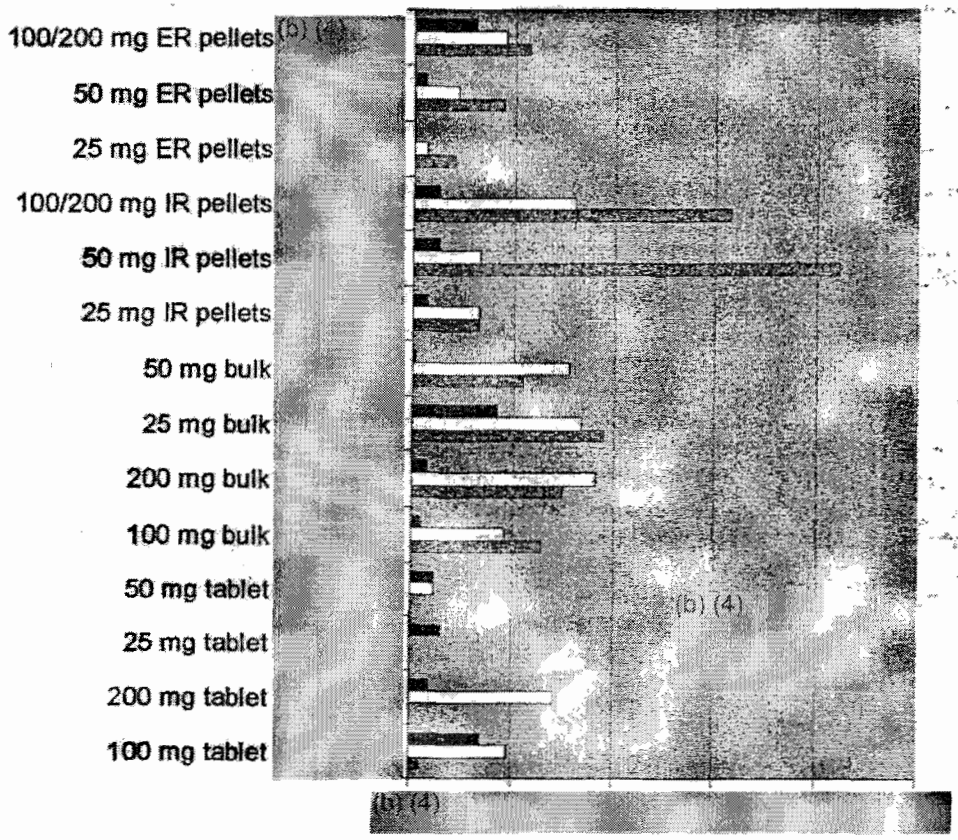
Metoprolol Manufacturing Issues
Since the FDA approval dates



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Product	OOS	NCR Initiated	Lots Rejected
100 mg tablet (b) (4)	(b) (4)	(b) (4)	(b) (4)
200 mg tablet			
25 mg tablet (			
50 mg tablet (			
100 mg bulk (			
200 mg bulk (			
25 mg bulk (b) (4)			
50 mg bulk			
25 mg IR pellets (b) (4)			
50 mg IR pellets			
100/200 mg IR pellets (b) (4)			
25 mg ER pellets (b) (4)			
50 mg ER pellets			
100/200 mg ER pellets (b) (4)			

The OOS test reports included but were not limited to the following: *Assay; Loss on Drying; Dissolution; Content Uniformity, and Particle Size.*

The NCRs included but were not limited to the following: *Foreign Tablet; unapproved deviation; Speed Study; Failed AQL-broken tablet; Omission of IR Pellets; Expired ER pellets, Content Uniformity; Metal shaving found on* (b) (4) *Press; IR pellet Particle Size; Sample Prep error; and ER pellet particle size.*

b. There is insufficient evidence to support the release of Metoprolol Succinate 100 mg ER Tablets processed with active pharmaceutical ingredient (API), Metoprolol Succinate USP, which was different from that used in the designed process. Since your 05Aug2007 IR pellet validation study (07CRC-664 [R7] PE-14-08) using the Mexican Intermediate of Metoprolol Succinate in the production of 100mg and 200mg tablets, you have had approximately (b) (4) NCRs relating to particle size. The particle size of post-validation lots of this API, are smaller than the particle size of the API used in the 2007 validation study.

You continued to manufacture and distribute approximately (b) (4) lots of these tablets until 17Oct2008, when you ceased production. The IR and ER pellet batches used in the tablet batches have sporadically failed particle size tests since that

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time. In fact, since 03Jul2008, 23 IR Pellet batches were rejected for particle size problems. You have also released several batches of Metoprolol Succinate 100 mg ER Tablets manufactured using the API lots received with a changed, smaller particle size that had been received prior to 03Jul2008. These include batch #'s [redacted] manufactured in July of 2008 to mid October 2008, using Pellet lots that had included API lot #'s [redacted]

c. You failed to take appropriate corrective actions after investigational findings identified the root cause for dissolution failures of Metoprolol Succinate ER Tablets, 50 mg. During the 06Aug2008 investigation of NCR #'s 14969 and 14181, you identified excessive press speed [redacted] to be the root cause of the dissolution failures for lot #'s 93394 and 93862. This data brings the validation study, (08WP70369 00 [R1] PV-07-01), under suspect, in which the press speed range is [redacted] In addition, you continued to operate at press speeds of [redacted] and released approximate [redacted] lots of Metoprolol Succinate Tablets 50mg from 06Aug2008 to the time of this inspection.

d. Rework by re-screening due to unacceptable particle size, was performed in August 2007, without change control, QA approval and validation, on IR pellets lot# 87843 (C-664) used in the manufacture, release and distribution of the following [redacted] Metoprolol 100 mg/200 mg tablet batches, lot #'s: [redacted] Further, a pre-approval supplement was not pursued for this rework process nor was this rework process submitted in the Annual Report dated 05Jul2008. Notes from an upper management meeting indicate the re-screened product cannot be used for commercial sale until the pre-approval supplement is approved.

Hydromorphone HCl Tablets

e. [redacted] batches of Hydromorphone HCl IR 4mg Tablets on the market within their expiry, were manufactured utilizing an un-validated, auto-fill process. The batches are lot #'s [redacted]

Validation batches manufactured Dec2005 and Jan2006, failed to demonstrate control and reproducibility; blend uniformity and potency failures occurred. Modifications were made to the compression stage of the manufacturing process and a new validation study was performed in Jun2006 with acceptable results. The modifications included decreasing the press speed during compression to [redacted] and using a manual hand fill process for transferring the blend to the press hopper. The Auto-Fill powder transfer system which is a vacuum system used to transfer the powder blend to the tablet press hopper was previously used. The master batch record was not revised to require the blend to be hand fed to the tablet press resulting in all [redacted] batches manufactured from Jun2006 to Aug2008 being manufactured using the Auto-Fill transfer system instead of hand filling.

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The validation study was also flawed:

- There is no documentation of the times the samples were collected to ensure adequacy of compression across the batch.
- Discrepancies were noted in the data for tablet hardness samples collected at various hardness levels. The validation protocol required collecting samples at (b)(4) for dissolution, weight variation, hardness, thickness and friability testing.
  - The samples at target hardness of (b)(4) collected from lot #'s 72722 and 73523 ranged from (b)(4) respectively.
  - The samples collected for (b)(4) from lot # 73523 ranged from (b)(4)
  - Samples were not collected at the (b)(4) due to "the fact that no tablets compressed at (b)(4) level exhibited proper physical characteristics for weight and thickness specifications stated in the MBR." However, the master batch record was not revised to change the hardness range which is currently (b)(4)
- During compression of one the validation batches, lot # 73523, to evaluate tablets at a press speed of (b)(4) the press was run at a speed of (b)(4) which equates to about (b)(4) tablets. There is no documentation of this in the validation report, data or batch record or of the disposition of these tablets.

AQL Failures for Tablet Products

f. You have failed to adequately study causes for the acceptable quality limit (AQL) failures which occur across product lines and include among others, nutritional, Metoprolol Succinate and Morphine family products. The AQL encompasses statistical sampling to evaluate aesthetic tablet defects, setting limits on the amount of statistically acceptable defects per batch. Despite changes to manufacturing equipment in tablet coating, product failures continue. This brings into doubt the validation of this process step for all coated products and the quality of products on the market. Investigations exist which occasionally list upstream manufacturing of core tablet issues as possible causes to coated tablet failures. Some of these encompass, hardness, % loss on drying of the granulation, compression speeds and compression force. None of these issues is adequately investigated to determine the root cause and instead coating is solely blamed with system upgrades.

AQL failures are summarized as evidenced by

1) (b)(4) bulk batches spanning a 4 ½ month period from 18July2008 through 7Nov2008 of the Morphine Sulfate ER and IR families, failed to perform as validated during compression and coating due to AQL failures. (b)(4) of those batches were (b)(4) re-inspected for AQL; on average about (b)(4) of all re-inspected batches were discarded; in one instance (b)(4) of the batch was discarded. The acceptable portions were subsequently released for further processing, packaging or were sold (b)(4) total batches were sold, at close of the inspection several were still

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awaiting a disposition). The investigation did not extend to complaints received for batches manufactured in this period. Forty-eight complaints have been received concerning tablet defects. The size of the AQL sample for routine batches has not been increased to evaluate and ensure the effectiveness of the corrective actions. The probable cause of the failure was identified as problems with the air handling unit for the coating pans and upgrades to the air handling system were completed in Dec 2008. Some batches which failed specifications during the compression and coating process are (note: this table is not all inclusive):

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Date	Morphine Sulfate Product	Batch	NCR	Percentage waste from re-inspection	Reason
7/7/08	60 mg ER	91290	15810	Inspection data not available; missing from batch records	Fails sorted AQL for surface spots and code number illegible/incomplete
7/18/08	60 mg ER	95572	15360	(b)(4)	Failed AQL for defect
7/18/08	60 mg ER	95573	15384	Rejected; not inspected	Code number illegible/incomplete; local erosion
7/27/08	30 mg ER	94421	15553	Inspection data not available; missing from batch records	Failed sorted AQL; tablet not uniform in color/color variation
8/2/08	60 mg ER	95575	15682	(b)(4)	Fails AQL for illegible code and broken tablets
8/6/08	60 mg ER	97337	15729		Fails AQL for tablets not smooth
8/22/08	30 mg ER	97332	15993		During coating pan failed AQL for tablets not smooth, illegible debossing
8/28/08	60 mg ER	97340	16119	Rejected; not inspected	Fails AQL for illegible code
9/4/08	60 mg ER	98019	16220	(b)(4)	Fails AQL for incomplete code
9/9/08	30 mg ER	97335	16339	(b) (full inspection data not available; missing from batch records)	Failed AQL for not smooth and illegible tablets
9/11/08	15 mg ER	98757	16397	(b)	Failed AQL for not smooth and illegible tablets
9/12/08	15 mg ER	98758	16400	Rejected; not inspected	During coating pan failed AQL for tablets not smooth, illegible debossing
11/6/08	15 mg ER	99751	17418	Inspection data not available; missing from batch records	Failed AQL for not smooth and illegible tablets and not uniformly polished
11/6/08	60 mg ER	99766	17433	(b)(4)	Failed AQL for not smooth tablets and illegible codes
11/708	15 mg ER	100553	17464		Failed AQL for not smooth tablets and illegible codes
11/7/08	15 mg ER	100554	17465		Failed AQL for not smooth tablets and illegible codes

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2) The table below summarizes [redacted] bulk batches of Prenatal Rx1 Multivitamin Tablets spanning from Oct 2008 through Dec 2008. These batches failed AQL inspection after coating. The investigation did not extend to complaints received for batches manufactured in this period. Fifteen (15) complaints have been received concerning tablet defects in 2007 and 2008. Finally, the size of the AQL sample for routine batches has not been increased to evaluate and ensure the effectiveness of the corrective actions.

Batches which failed specifications during the compression and coating process are:

Date Coated	Bulk Batch/ Pkgd. Batch	NCR	Reason	Percentage waste from re-inspection	Listed Probable Cause of Failure
12/10-11/08	102121	17967	Local erosion, surface blemishes chips & adhering spots	[redacted] pans manufactured are rejected; [redacted] doses or nearly [redacted] of total batch	Process formulation issues--amount of Disintegrant in coating solution
6/09/08 & 10/ 3,7-8&20/08	95495/ 97487	14774	Surface blemishes & not uniformly polished	[redacted] of reinspected portion	Tooling, compression & coating parameters not optimal (CAPA 15456)
6/3-4&608	95493	14674	Surface blemishes, chipped tablets & illegible codes	[redacted]- All rejected no inspection	Tooling, compression & coating parameters not optimal (CAPA 15456)
5/30-6/2/08	95492/ 95279	14635	Surface blemishes & illegible codes	[redacted] of reinspected portion	Tooling, compression & coating parameters not optimal (CAPA 15456)
5/29-30/08	95491/ 95280	14623	Surface blemishes & illegible codes	[redacted] of reinspected portion	Tooling, compression & coating parameters not optimal (CAPA

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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DATE(S) OF INSPECTION
12/15/2008 - 02/02/2009

FEI NUMBER
~~1937079~~ 3007259359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. David A. Van Vliet, Interim President and Interim Chief Executive Officer

FIRM NAME	STREET ADDRESS
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					15456)
9/23/08	95489	16601	Erosion, surface blemishes & illegible Code	(b) All rejected no inspection	Changes in coating parameters under planned deviation.
5/20/08	95488/ 95276	14526	Surface blemishes, breaks, chips and illegible codes	failed (b) pans; (b) (4) of total batch	Product formulation and manufacturing process
4/23-24/08	94192/ 95275	14036	Not fully covered, breaks, not smooth, illegible code	(b) pans rejected; (b) of total batch	Operating Pan Air Flow & Spray Rate at the minimum control limits of (b) (4)
3/8-14/08	92360/ 91751	13271	Local erosion	(b) of reinspected portion	Improper dedusting
1/27-28/08	91270/ 91752	12636	Local erosion & surface blemishes	(b) (4) of reinspected portion	Inadequate process parameters (low pump rpm & spray rate)
1/26-27/08	91269/ 91749	12615	Tablets not smooth and not fully covered	(b) of reinspected portion	Equipment Failure during coating
1/2-5/08	88707/ 89081	12306	Local erosion, surface blemishes, chips	(b) of reinspected portion	Inadequate temperature in the coating pan
12/10-11/08	86593/ 91695	12034	Local erosion & surface blemishes	(b) (4) of reinspected portion	Inadequate heating of tablets during coating
10/31-11/1/07	86594/ 87759	11622	Surface blemishes, chips, breaks & tablets not smooth	(b) of reinspected portion	Inadequate heating of tablets during coating

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OBSERVATION 3

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically,

a. There was no investigation into conflicting assay results between the release bead uniformity potency results for Metoprolol Succinate ER pellet batches, which were lower than target but within specification, and the results from a second subsequent test on a composite (retain) sample, performed under special request by the production department. There is no raw data for the composite sample results collected under this special request. These composite results were higher than the original bead uniformity results for (b) (4) C-759 pellet batches (lot #'s (b) (4) (b) (4) batches of Metoprolol Succinate ER Tablets 23.75 mg, were manufactured in July and August of 2008, using the composite potency values from the pellet batches rather than the bead uniformity potency results. No evaluation has been performed of validation data to ensure 23.75 mg tablets will meet specification when blended with pellets with potency values below the target blend uniformity specification limit.

b. No investigation to determine the root cause was performed for the following incidents:

- Metoprolol Succinate ER pellet batch, lot # 98459 (47.5 mg tablets) which failed dissolution testing and was confirmed by OOS (# OOS-08-SEP-012). NCR # 17634 was initiated 17Nov2008.
- Potassium Chloride bead batch, lot # 99938 which was confirmed to be OOS (#OOS-08-SEP-005) for time release dissolution. The results were outside of the proven acceptable range at hours (b) (4) NCR #16706 was initiated 29Sep2008.
- Potassium Chloride (KCl) blend batches, lot #'s 99900 (OOS-08-OCT-017) and 99910 (OOS-08-OCT-045) which were confirmed OOS for timed release dissolution on 30Oct2008 and 04Nov2008, respectively. NCR #17397 was initiated for both lots on 05Nov2008.
- Complaints of "black spots" and "moldy looking areas" were received for PreCare Premier prenatal vitamins; batch #'s 76051, 91544, 90006, 79697, 91545, 95301. At least eight (8) complaints of this nature were listed for lot 90006 alone, yet a letter was sent to a complainant stating this was an "isolated incident."

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OBSERVATION 4

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

a. Corrective and preventive actions have not been carried out regarding NCR 12156 when Hydromorphone HCl Tablets 2 mg, lot 82575 failed the acceptance criteria for content uniformity in Dec 2007. The NCR determined the cause was segregation due to the use of the Auto Filler to transfer the powder blend into the press hopper. The report states (b)(4) (b)(4) (b)(4) The master record was not revised until July 2008 with the correction being implemented in September 2008. During that time numerous batches were manufactured using the Auto Filler; [redacted] of these remain within their expiry period.

b. Corrective actions were not taken to rectify a systematic problem allowing compression prior to verification of acceptable blend uniformity data for products including Oxycodone HCl. QA approval of the blending process prior to compression is required. For example, Oxycodone HCl lot # 96621 was blended on 23Jun2008 and compressed on 24Jun08. The batch failed blend uniformity on 08Jul2008. An investigation indicates the cause was sampling error yet no re-sample could be taken to confirm or refute the results because the batch had been compressed.

c. No corrective or preventive action has been recommended concerning NCRs 14181 and 14969 which were initiated for lot #'s 93394 and 93862 of Metoprolol Succinate ER Tablets 47.5 mg which failed dissolution. The NCRs identify the root cause of the failures as *"Excessive speed on the tablet press"* despite, press speed range specified in the master record of (b)(4) The batches continue to be manufactured at a press speed of (b) Approximately [redacted] batches have been made since this time.

d. Appropriate corrective and preventive actions were not taken when problems were encountered with cap torque during packaging of Prednisolone 5mg/5mL, lot #96179. The investigation did not extend to other affected product lots.
   - CAPA # 16409 opened 12Sep2008 stated the vendor was previously disqualified from producing any more closures due to significant quality issues. However, you continued to use this supplier's closures.
   - Personnel were not trained to document quality issues at the time of occurrence. Information in NCR 15949 initiated in response to this cap torque problem indicated that closure P5303 has always been problematic; yet, the problems have not been documented in the past.
   - Additional monitoring of torques during packaging was not conducted for lots 10568, 10569, 1023471, 102372, 102373 and 102374 as instructed in CAPA 16409.

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e. After compressing Prenatal Rx1 Tablets lot # 95489 in May of 2008, compression tooling was found damaged with chips and broken keys. The cause was attributed to exceeding the allowable compression force of the tooling. The tooling is rated for (b)(4) of compression force and the press was set at (b)(4). The compression force is a critical parameter but is not recorded in batch records. The master and batch production records have not been revised to specify the tooling rating and to require documenting the compression force.

f. Corrective actions per CAPA 17038, to (b)(4) specification and to revise the MBR for input adjustment of Prednisolone USP based on potency for Prednisolone Syrup, USP, 5 mg/5mL were not implemented. Stability data showed potency results trended downward through product expiry.

g. No CAPA follow up or master batch record (MBR) revision has been documented concerning, NCR 16469 opened on 16 Sep 2008 for Morphine Sulfate ER 100 mg tablets. The NCR captures excursion outside written procedures where bulk batch # 97343 was not compressed within the (b)(4) limit as stated in the batch record.

The NCR discussed that the limit was not established according to stability data and a CAPA, #17728, 24 Nov 2008, was opened to revise the hold time in the MBR between blending and compression.

h. No corrective and preventive action was initiated for OOS-08-OCT-038 when a supervisor and data auditor failed to note the total recovery for the timed release dissolution was out of range for Potassium Chloride bead lot # 100098. The data auditor and supervisor failed to realize the lot should have been retested due to total recovery of the potassium chloride being out of specification and retraining should have been conducted for failure to recognize the need to retest.

i. There is a failure to implement corrective and preventative actions or follow up on investigations concerning several products which are not limited to Morphine Sulfate Tablets, Metoprolol Succinate ER Tablets and Prenatal Rx1 Tablet AQL coating failures (surface blemishes, chips, breaks, erosion, rough surfaces, illegible code, etc.). Issues are identified in non-conformance reports. Trending has identified repeated failures for tablet defects. Yet, AQL tablet coating failures persist despite coating equipment upgrades, and equipment qualification.

Notably,

- When Prenatal Rx1 bulk tablet batch # 86594 (packaged lot # 87759) failed the AQL in Nov2007, the cause was attributed to inadequate heating of the tablets during the coating process; however, there is no evidence to support this conclusion. Process parameters used to process the tablet pans which failed were similar to other pans which passed and were released.

- When Prenatal Rx1 bulk tablet batch # 91270 (packaged lot # 91752) failed the AQL in Jan 2008 for local erosion

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and surface blemishes, the cause was attributed to inadequate process parameters during tablet coating which affected tablet appearance (low pump rpm and spray rate). However, these are the batch operating parameters specified in the MPR (master production record).

- Prenatal Rx1 bulk tablet lot #'s 86593 (packaged lot # 91695) and 88707 (packaged lot # 89091) failed the AQL on 11-12Dec2007 and 03-05Jan2008, respectively. Root cause was determined to be inadequate temperature in the coating pans. CAPA 12429 was initiated to replace the temperature probes and display for the coating pans yet they have not been replaced on coating pans (b)(4) which were used for these batches.

- Prenatal Rx1, bulk tablet lot #'s 95491 (pkgd. lot 95280), 95492 (pkgd. lot 95279), 95493 (rejected) and 95495 (pkgd. lot 97487), failed the AQL, 29May2008 - 09Jun2008. The cause was attributed to a combination of tooling, compression and coating parameters not optimal for this product. CAPA # 15456 was initiated 23Jul2008 to evaluate and modify as appropriate the tooling, compression and coating parameters. To date this CAPA has not occurred.

- Prenatal Rx1 bulk tablet lot # 94192 (pkgd. lot 95275) failed the AQL in April 2008. The investigation indicated there is an ongoing project to improve/replace coating equipment and to review and improve all coating record parameters and instructions. The coating equipment has since been upgraded and has undergone qualification; yet the product process parameters have not been reevaluated nor revalidated with new coating parameters.

- During packaging of Prenatal Rx1 Tablets, bulk batch # 95488 (pkgd. lot 95276), operators noted unacceptable tablets. A second AQL sample was collected in April 2008 and (product pans of failed. Tablet weight and hardness checks performed during compression of pans (b) were low but were within the acceptable limits. The cause of the defects was not determined; however, the product formulation and manufacturing process were identified as "strong factors." Follow up states the Research and Development and Operations departments will define appropriate parameters to use in the coating process for this product. The coating equipment has been upgraded and has undergone qualification; yet the product process parameters have not been re-evaluated nor revalidated with new coating parameters. The CAPA is still open pending validation approval.

- Metoprolol ER Tablets, 23.75mg, lot # 95931 failed the AQL for broken tablets in July 2008. The ARN (Analytical Research and Development) department determined the coating process should begin when the exhaust temperature meets (b)(4) due to Metoprolol sensitivity to heat yet no corrective action was taken. The batch record currently specifies a start exhaust temperature range of (b)(4)

- NCR 15223 was initiated for Metoprolol Succinate ER Tablets, 47.5mg, lot # 93933 when the tablets failed the coating AQL in July 2008. The investigation determined the most likely cause was due to reduced air flow during the coating process. The batch was processed using a pan air flow of (b)(4) The target is (b)(4) with

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control limits of (b) (4) and an operating range limit of (b) (4) The investigation did not extend to other batches processed at (b) (4) Operators were trained to keep the air flow in the pan at a high rate and at the established targets, yet the batch record was not revised to reflect this requirement. The investigation also did not extend to the core tablets which were observed with similar 'not smooth' areas on the bisect side of the tablet and edge erosion.

- NCRs 10374 (Morphine ER 200 mg tablets), 17418 (Morphine ER 15), 17464 (Morphine ER 15), 17465 (Morphine ER 15), 9363 (Morphine ER 15) all cite numerous reasons for tablets failing AQL, and content uniformity, including but not limited to low LOD % (loss on drying), tablet hardness, changes in recipe, blending and granulation parameters etc. None of the above NCRs adequately followed each of the suspected root causes to investigation completion to obtain definitive results regarding the actual root cause of the failures. The coating process is instead blamed as the causative factor in all prior and subsequent AQL failures. Despite coating pan upgrades, Surface AQL failures persist.

- Identified "possible" root causes of tablet hardness linked to coating issues was not fully investigated. NCR 15810 (12 Aug 2008) was opened to investigate AQL failures of bulk batch # 91290, Morphine ER 60 mg tablets (packaged lot 91765). The NCR Root Cause Analysis states: (b) (4) (b) (4) The investigation failed to examine the hardness issue; no other investigations were opened to address this issue.

- NCRs 17464 and 17465 were opened on 7Nov2008 for Morphine Sulfate ER 15 mg tablets lot #'s 100553 and 100554 documenting AQL failures for coated tablets. A planned deviation 17297, 30Oct2008 was opened to address changing Pan Air Flow parameters from a target of (b) (4) control limits) to a target of (b) (4) (control limits of (b) (4) A change initiation form (CIF) was opened 30Oct2008 to correct the batch (A)cord with the new Pan Air Flow parameters, but as of 06Jan2009 the MBR has not been updated, and the CIF has been closed.

OBSERVATION 5

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

a. You failed to extend an investigation on oversized Potassium Chloride 10 mEq Capsules to products currently on the market. The ongoing investigation starting 21Nov08 and concerning lot #'s 99906, 99907 and 99908, stated your weight

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sampling procedure was unable to assure that 100% of the distributed encapsulated products were within specifications. These additional products include: Pangestyme CN20, Pangestyme MT16, Pangestyme UL18, Pangestyme UL20, Disopyramide, Potassium Chloride 10 mEq, Micro-K 8 mEq, Micro-K 10 mEq and Potassium Chloride 8 mEq.

b. The investigation of complaint # 17365 concerning an oversized tablet of Hydromorphone HCl USP, 2 mg, packaged lot # 90219, did not extend to other Hydromorphone HCl 2 mg batches to determine if Compression Events logs document the production of oversized tablets. During the investigation, the compression event log was reviewed and found the Main Compression Roll and Dosing allowed for the production of oversized tablets during set-up, which is believed to be due to failure to accept the recipe settings prior to the addition of powder to the hopper.

c. There was a failure to thoroughly investigate discrepancies in stage testing investigations in which the results were invalidated due to "injection error." Identified injection error did not prompt all other injections from the same lot and other lots run on the HPLC to be re-run to determine the extent of the error. Examples include invalidated data for the following:

- Metoprolol IR beads, C-735, lot# 95795, sublot G-blend uniformity samples (b) (4) blend uniformity samples (Stage Testing (ST), ST-08-JUL-001).
- Metoprolol IR beads, C-664, lot# 95005EF-blend uniformity sample (ST-08-JUL-003).
- Metoprolol IR beads, C-735, lot# 97059D-blend uniformity sample (ST-08-JUL-006).
- ST-38-JUL-007 on Metoprolol IR beads, C-735, lot# 97059F-blend uniformity sample
- ST-08-SEP-005 on Metoprolol ER, C-665, lot# 98454-blend uniformity samples (b) (4) and lot# 98462 (on the same HPLC run) blend uniformity samples (b) (4)
- ST-08-SEP-015 on Metoprolol IR beads, C-664, lot# 98478 A/B-blend uniformity sample
- ST-08-OCT-004 on Oxycodone IR blend lot# 97443-blend uniformity sample
- ST-08-DEC-10 on Metoprolol ER beads, C-665, lot# 102834-blend uniformity sample

OBSERVATION 6

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

a. Investigations, 9209 and 9820, conducted 06Feb2007 and 01May2007 respectively and covering several batches of Histinex HC Syrup packaged with an incorrect closure, were deficient. In Feb2007, Histinex batches were packaged, in part, using closures which did not have the required foil liners. A partial shipment of faulty closures was received from the vendor. Part of the shipment had an incorrect liner in the cap while the other portion of the shipment contained the

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specified cap liner. The lot of closures in question was vendor's lot # 200623449770. The investigation was closed on 16May2007. (b) (4) batches of Histinex were packaged using this lot of closures and were subsequently released ~~based on a flawed stability study~~. The investigation did not extend to other lots of closures from the same manufacturer, in-house at the time of this investigation.

A second incident occurred on 01May2007. Closure lot # 20070376381 which was received from the same manufacturer on 09Feb2007 contained closures which were again mixed containing the correct and incorrect closures. These closures were once more used to package (b) (4) lots of various drug products; four of which were distributed between 3/20/07 and 05/03/07. The (b) (4) batches included Histinex HC Syrup lots (b) (4) NCR 9820 states an MRB (material review board) will convene to evaluate the four distributed lots. There is no evidence that this occurred.

b. In response to the above investigation a corrective action was initiated to ascertain which bottled lots contained the correct cap. This was to be carried out by using the metal detection system which would identify correctly bottled product. This was performed in June 2007. The corrective action was deficient. Lot # 79677 was not evaluated with the metal detection system as required in the planned deviation report # 9946.

c. No root cause has been identified for (b) (4) batches of Metoprolol Succinate ER Tablets 23.75 mg, which failed dissolution. Lot #'s 95927, 95929, 95930, 95931, 95932, 95933 and 96880 were compressed in July of 2008. Investigations to determine the cause for the dissolution failures were not initiated or were untimely. For example, the investigation into lot # 95931 has not been initiated, the investigation into lot #'s 95929, 95930, 95932 and 96880 were not initiated until 17Dec2008 and are currently open, and the investigations for lot #'s 95927 and 95933, opened 22Sep2008 and 29Oct2008 respectively, have not been completed.

d. The investigations were not timely after (b) (4) batches of Metoprolol Succinate ER Tablets 23.75 mg, lot #'s 93680, 93681, 93684 and 93685 failed dissolution in May 2008. The NCR # 14285 which was initiated on 06May2008, was not completed until 15Aug2008. Investigation 14337 for NCR #14285 was not completed and approved by Quality until 15Aug2008.

e. On or about 08Jul2008, Metoprolol Succinate 23.75 mg ER tablets lot # 95928 failed dissolution at the (b) (4) interval at (b) (4) (specification is (b) (4) An NCR #16532 for this failure was not initiated until 19Sep2008 and investigation # (~~1~~0)639 was not completed and approved until 18Dec2008; the NCR remains open.

f. You failed to adequately investigate and follow up NCR 14908 which was opened 18Jun2008 for Morphine ER 100 mg tablets lot # 96669. The NCR documents chipped tooling (tool set (b) (4) during compression which was replaced with tool set (b) (4) An associated investigation, (b) (4) documents (b) (4) issues to examine and review-tooling history, tooling destruct(~~ion~~), bulk batch tooling set up for lot # 96669, and dies and die locks used for lot # 96669. No documentation of

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the last two issues concerning set up or review of dies and die locks exists.

The investigation failed to expand the inquiry into why the tips were chipping. Review of the compression tool record for tool sets (b)(4) shows a maximum tip force for the tooling set at (b)(4) The recipe report for the (b)(4) for Morphine ER 100 mg tablets, sets the control parameters for Max Punch Force at (b)(4) No investigation is documented to see if the force control went outside (b)(4) during the compression run and the Event Log report for the entire run is unavailable.

g. NCR #'s 13657, and 13699 were initiated on 2Apr2008 and 7Apr2008 respectively, which document under and overage yields outside the (b)(4) stated specifications for Morphine Sulfate ER 60 mg lot # 91290. Scale equipment failure is cited as the causative factor for the overage OOS, however, no investigation into the equipment failure was performed, rather a new scale was used to reweigh material.

h. The investigation was not timely when Hydromorphone HCl 2mg Tablets lot #'s 97847, 97846 and 97848 tested out of specification for blend uniformity on 06Oct2008. The OOS investigation was completed on 14Oct2008. A non-conformance report was initiated on 27 Oct 2008. The investigation has not been completed to date.

i. Your investigations failed to determine the exact source and nature of metal found in drug products manufactured between 7/22/08 and 12/24/08. The metal contamination was found during manufacturing operations in at least (b) batches observed in at least four different products.

Your investigations state possible sources of this metal contamination are raw materials (b)(4) and (b)(4) used to manufacture over 20 different products. As part of your investigation you initiated NCR 17072 for Oxycodone HCl 5 mg, lot 98065. The NCR states (b)(4) (b)(4) But, you failed to initiate an investigation with the raw material supplier for (b)(4) until questioned during this establishment inspection.

OBSERVATION 7

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically,

a. You failed to submit a field alert report to the FDA within three working days for Potassium Chloride Extended Release Capsules lot #'s 99906, 99907 and 99908 as required in procedure 211.100.90 "FDA Field Alert Reporting." Overfilled capsules for these batches were found on 21Nov2008 and not reported to FDA until 06Jan2009.

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b. As part of your investigation of oversized Morphine Sulfate tablets, which was initiated on/about 15May2008, you sorted all tablet products on hand and found oversized tablets with at least 10 more products. No field alert was ever filed and FDA was not notified until 10Oct2008. Products include:

- Isosorbide 30 mg and 60 mg
- Propafenone HCl Tabs 150 mg and 225 mg
- Dextroamphetamine Sulfate Tabs 5 mg
- Plaratase 8000 Tabs

OBSERVATION 8

An annual report did not include a full description of the manufacturing and control changes not requiring a supplemental application, listed by date in the order in which they were implemented.

In a 11Apr1997 Annual Report, there is no explanation or justification for changing time release dissolution specifications for Potassium Chloride ER granules from those referenced in previous annual reports. Currently, when Potassium Chloride ER granules are tested for time release dissolution and the results are not within the specifications, they are compared to PAR (proven acceptable range) specifications which are broader. If results are within PAR, the lot is accepted for further processing of the Potassium Chloride Capsules with no investigation. The specifications are as follows:

PAR Specifications	Specifications
(b) (4)	(b) (4)

The 2008 annual report neglected to reflect a change in the method for Potassium Chloride ER granules allowing the release of in-process material without investigation as long as results are within PAR specifications. Numerous batches which were outside the specification but within PAR have been released with no investigation. For example, ER granules lot #'s 91918 and 91931 were outside the specification but within PAR for (b) (4) No investigation was performed. The ER granule lots were further processed as packaged lot 91830 in Feb2008 and were subsequently released.

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OBSERVATION 9

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, sorting processes are deficient. On 16Mar2008 per NCR 13360, bulk batch # 91290, Morphine ER 60 mg tablets failed AQL due to broken tablets. The batch was (b) re-inspected for AQL failures and passed this initial post-inspection. The product was packaged into finished product lot 91765.

Per the gauge sorting project for oversize tablets the packaged product, packaged batch 91765 (bulk batch 91290) was de-bottled and a second, subsequent sort occurred on 7Jul2008. This successive sort of the packaged lot, revealed tablets again failed AQL for surface spots and illegible or incomplete code number.

This second AQL failure was not discovered nor caused a batch rejection during the initial sampling and testing performed in March.

Additionally, two other NCRs 13657, and 13699 were initiated on 2Apr2008 and 7Apr2008 respectively, which document under and overage yields outside the (b)(4) stated specifications. Neither of these instances of failure caused the batch to be rejected, at the time the NCRs were initiated and closed out.

OBSERVATION 10

Rejected closures are not controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically, you failed to quarantine Applicator Caps lot#123095 for the product Clindesse/Gynasole-1, per NCR #18177, dated 29Dec2008. These applicator tips jammed the production line due to extra flashing on the bottom portion of the cap, resulting in a rough surface. During the inspection, 16Jan2009, the status of the applicators was investigated and found to be in "approved" status for use.

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OBSERVATION 11

Returned drug products held, stored or shipped before or during their return under conditions which cast doubt on their safety, identity, strength, quality or purity are not destroyed.

Specifically, the reason for the return on 10Jun2008 of [redacted] units of Metoprolol 100 mg, lot #74289, was not documented. This order was initially processed on 17Aug2007. Further, there is no documentation of the storage temperature for the tablets while out of your possession. According to the "Processing of Returned Goods" form dated 10Jun2008, this product was returned to stock without investigation of storage conditions and the resultant effect on the tablets.

OBSERVATION 12

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, you failed to follow your SOP 211.198.8.1.1, which states that consumer complaints shall be closed 45 days of initial entry of the product complaint into the system. Customer complaint numbers 16789 and 16463 for Potassium Chloride 750 mg capsules were opened respectively on 11/6/08 and 10/16/08. On 1/21/09, these two complaint files had yet to be closed by the persons responsible to close the investigation. Both of these consumer complaints were due to a foreign object found in a single capsule at the consumer level.

OBSERVATION 13

Changes to written procedures are not reviewed and approved by the quality control unit.

The procedure on QC general laboratory techniques, submitted for approval 14Feb2008 through the change control process as #12906, was not approved until 17Dec2008. This delay resulted in two laboratory investigations, #'s OOS-08-JUN-048 dated 26Jun08 and ST-08-SEP-010 dated 26Sep08, concerning the incomplete transfer of sample material for Hydromorphone HCl blend lot #'s 95531, 95532 and 97846.

PACKAGING AND LABELING SYSTEM

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OBSERVATION 14

Inspection of the packaging facilities immediately before use is not done to assure that all drug products have been removed from previous operations.

Specifically, line clearance practices are deficient. Nearly 100 NCRs document "Foreign" tablets and other materials found in rooms and on packaging lines during 2007, despite SOPs and work instructions which outline and define pre- and post-inspection procedures. Trending was performed per "EC IV Line Clearance NCR's" graph and CAPA implemented, however, NCR's continued to be document through 2008 and January 2009; at least 72 new NCR's were logged during 2008 after CAPA implementation in August-Nov 2007.

OBSERVATION 15

Examination of packaging and labeling materials for suitability and correctness before packaging operations is not performed.

You continued to use packaging components supplied by the company [redacted] which was disqualified as a result of your 29May2007 vendor audit without adequate justification. Between 11Sep2008 and 07Nov2008, you continued to package and distribute drug products with closure items, stock numbers P3056, P2772, P27772, manufactured by (b)(4) which were used to package among others, the following products: Metoprolol Succinate ER Tablets 50 mg; Potassium Chloride ER Tablets, 1500 mg; Potassium Chloride ER 750 mg Capsules; Hydrocodone Bitartrate/APAP 16oz/15mL; Prednisolone Syrup 5 mg/5 mL; and Prednisolone Sodium Phosphate Syrup 15 mg/5 mL.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 16

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a. Cleaning at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity

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of the drug product has not been sufficient to mitigate foreign material during manufacturing.

At least thirty (30) NCR's in 2008 and twenty-four (24) NCR's in 2007 document escalating issues with the discovery of foreign tablet and materials at various stages of manufacturing from blending through compression and up to the point of packaging. Though several changes to gowning procedures and personnel flow have been implemented, trending has not occurred in the manufacturing departments, and no formal CAPA has been initiated.

b. **Sanitization of hoses used in drawing purified water from the closed loop, continuous circulation system does not occur weekly as regularly scheduled per SOP 211.48.01 "Use, Maintenance, and Sanitization of Purified Water USP Point-of-Use Valves and Hoses." Additionally, water ports which are used more frequently are not sanitized at a more frequent rate.**

For example, during a documented two month period beginning 01Nov2008 through 31Dec2008, numerous deficiencies exist concerning lack of hose sanitization within a 7 day period. An NCR, #17997, occurring on 09Dec2008 was initiated after coliform bacteria were found in a routine sampling at (b) in granulation room (b). The isolated organism was identified as *Pantoea* spp. Point of Use logs for (b) (4) show hose sanitization occurred on 30Nov2008 and again on 09Dec2008; (b) (4) between cleanings which is outside the time range specified per SOP 211.48.01 as referenced above. Other microbiological failures have occurred as noted in NCR #'s 13584, 14620, 17830, 17831 and 17839 at different plant locations including ECIV, ECIII, and Westport facilities indicating this is a global issue.

Further, you failed to sanitize hoses on the following ports during the dates listed:

- (b) (4) hoses sanitized on (b) (4) and again on (b) (4) (b) (4) between cleaning) with (b) points of use.
- Port (b) (4) hoses sanitized on (b) (4) and again on (b) (4) (b) days between cleaning).
- Port hoses sanitized on (4) and again on (4) days between cleaning).
- Port hoses sanitized on and again on days between cleaning).
- Port (b) Liquid Manufacturing; hoses sanitized on 10Nov2008 and again 25Nov2008 (b) days between cleaning).
- Port (4) Research and Development; hoses not sanitized from (b) (4) until (b) (4) (at least (b) days between cleanings).
- Port (b) (4) hoses not sanitized from (b) (4) (at least (b) days between cleanings).
- Port (b) (4) hose sanitization not documented at all between (b) (4) (at least (b) (4) days between cleanings)
- Port (b) (4) room (b) (4) hoses sanitized on (b) (4) and again (b) (4) (4) days between cleanings.)
- Port (b) (4) hoses sanitized on (b) (4) and again on (b) (4) days between cleanings.)

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OBSERVATION 17

Routine calibration of automatic, mechanical, and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

a. The following four instruments used in the monitoring of your USP purified water system are not calibrated or verified for accuracy.

- Calibration Group pH Meter, (b) (4)
- (b) (4)
- Flow Rate Indicator, (b) (4) A sticker denotes "Calibration Not Required", but this indicator is monitored in (b) checks on the "Westport USP Water (b) (4) Operations Log," (b) (4)
- Flow Rate Indicator, (b) (4) A sticker denotes "Calibration Not Required", but this indicator is monitored in (b) checks on the "Westport USP Water (b) (4) Operations Log", (b) (4) Unit Outlet". (4)

b. **There is no formal procedure describing calibration of the (b) (4) detergent dispensers used to prepare the** equipment cleaning solutions (b) (4)

c. **The manufacturer's inspection report which specifies the dimensions for punch and die set (b) (4) used to press** Hydromorphone 2 mg tablets, was not verified.

d. Specifically, Work Instruction **WI-2250-5001-00 "Set up of a (b) (4) does not require the tool match report to** be used as the lower punches are placed into the turret.

OBSERVATION 18

Records are not kept for the cleaning and inspection of equipment.

There is no documentation of cleaning the Auto-Fill transfer systems, a vacuum system used to transfer powder blends to the tablet press hopper and cleaning and use logs are not maintained for these systems. This system may be used for approximately 186 different products including but not limited to the following: Isosorbide ER Tablets 60 mg, Morphine Sulfate ER Tablets 100 mg and 200 mg, CareNatal Tablets, and Potassium Chloride ER Capsules, 20 mg.

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OBSERVATION 19

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically,

a. There is no cleaning procedure for the Auto-Fill transfer systems (b)(4) with the exception of the Autofiller for the (b)(4) (b)(4) Procedure #WI-CLN-0100-00 for cleaning the (b)(4) is deficient in that it does not specifically address the Autofiller, it only states to clean the "hoppers." It also does not describe how to clean the filler hoses or hopper filter on the Autofiller.

b. The investigation into microbial failures for cleaning validation swab samples collected from the (b)(4) tank after the production of Butaconazole Nitrate Cream 2.0%, was deficient. No additional swabbing for microbial contamination was performed after subsequent cleaning activities.

c. There is insufficient evidence to support adequate cleaning of small areas of equipment such as hoses, piping and valves where swabbing (b)(4) areas is required. Procedures require swabbing for micro, active then surfactant contamination without accounting for the possibility of overlapping samples. Specific examples include but are not limited to: (b)(4) steel tank bottom outlet valve, (b) filling pump body end cap and (b)(4) Applicator filler hopper drain tubes.

OBSERVATION 20

Written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs.

Specifically,

a. The results of visual inspection, cleaning and polishing performed on punch and die sets after use in production are not documented. There are approximately (b)(4) punch and die sets used in the manufacture of about 140 different drug and nutritional products.

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b. A Tool Match Report for punch and die set [redacted] used in the manufacture of Hydromorphone HCl Tablets, 2 mg, was not run to determine a new pairing when punches were destroyed. For example, upper punches #'s [redacted] from set [redacted] were destroyed in May and July and new pairings were not determined.

c. Lower punch [redacted] which is used to compress Metoprolol 25 mg tablets, was destroyed on 27May08 and a Tool Match Report was not run to determine a new pairing.

d. The use of tool set [redacted] for compressing PreNatal Rx1 Tablets batch # 95489 was not documented in the compression tool record.

e. The Compression Tool Record for punch and die set [redacted] used in the manufacture of Hydromorphone HCl Tablets, 2 mg describes the [redacted] use with batch number, quantity manufactured and machine number. However, there is no entry for the [redacted] No investigation was performed to determine what batch (if any) this punch and die was used on.

f. The compression tool record for punch and die [redacted] used to press Metoprolol 25 mg tablets does not document the machine number, set up initials and start by initials for use [redacted] No investigation was performed to determine why this information was not recorded.

OBSERVATION 21

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

a. There are no documented specifications for evaluating defects during visual examination of the tool and die sets.
b. During the observation of the equipment set up for Morphine IR 30 mg lot# 98774, on 15Dec2008, the technician used a [redacted] torque wrench to tighten the turret bolts. The SOP WI-2250-5001-00, "Set up of a [redacted] requires the use of a [redacted] torque wrench.

OBSERVATION 22

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, in-process materials, and drug products and to prevent contamination.

Specifically, the quarantine area and both DEA vaults at the Westport location were over-full with a variety of in-process and finished products preventing adequate cleaning, inspection, and normal movement.

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FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	12/15/2008 - 02/02/2009 FEI NUMBER ~~1937079~~ 3007259359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. David A. Van Vliet, Interim President and Interim Chief Executive Officer

FIRM NAME	STREET ADDRESS
KV Pharmaceutical Co Westport	2280 Schuetz Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-3411	Human Drug Manufacturer

LABORATORY CONTROL SYSTEM

OBSERVATION 23

The written stability program does not assure testing of the drug product in the same container-closure system as that in which the drug product is marketed.

(b) (4)

(b) (4)

(b) (4)

OBSERVATION 24

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Specifically,

a. Metoprolol Succinate ER pellets, product code C-759, lot #'s 96857 and 96858, for use in 23.75 mg tablets, were analyzed for dissolution on 01Jul08 and the raw data reviewed by a member of the data management team on 06Jul08. The review failed to identify the following discrepancies on the worksheet.

- HPLC is circled as being used for dissolution analysis when in fact the UV was used.
- The lot numbers (96957 and 96958) listed on the balance printout for sample weights do not represent the actual lot numbers (96857 and 96858) weighed.

b. The worksheet for dissolution analysis of Metoprolol Tablets 47.5 mg lot #'s 93973 and 94006 does not identify the equipment used as required. This worksheet was reviewed by a data auditor in Aug2008.

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OBSERVATION 25

Verification of the suitability of the testing methods is deficient in that they are not performed under actual conditions of use.

Specifically,

a. **The dissolution methods (#1-2115 and #9960) used for analysis of Metoprolol Succinate ER Tablets 50 mg, 100 mg and** 200 mg were not properly transferred to the Quality Control Laboratory from Analytical Research department after a significant change to the preparation of dissolution medium occurred in November of 2006.

b. The assay methods for determination of vitamin D3 in stability analysis of products such as Prenatal Rx, Advanced NatalCare and PrimaCare tablets have not been shown to be stability indicating. Also, unknown peaks appearing in chromatograms are not identified or quantified.

OBSERVATION 26

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, the quality unit has failed to review the supplier's laser particle size results for the active pharmaceutical ingredient (API) Metoprolol Succinate USP, to ensure this API meets the internal specifications of (b) (4) (b) (4) and has not qualified the supplier's capability to meet the internal particle size specifications.

OBSERVATION 27

Complete records are not maintained of any modification of an established method employed in testing.

Specifically, for the dissolution analysis of Metoprolol ER pellets lot numbers 96857 and 96858 performed on 01Jul08, the sample preparation was modified to use a sample weight approximately (b) (4) the amount specified in the method.

OBSERVATION 28

Established laboratory control mechanisms are not followed.

Specifically, the yearly preventive maintenance has not been conducted on HPLC (b) (4) as required by LOP 216.00,

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"Shimadzu HPLC Preventative Maintenance Procedure-QC." The last yearly preventative maintenance was performed on 12Oct07.

OBSERVATION 29

Laboratory records do not include complete records of the periodic calibration of laboratory instruments.

Specifically, the data used to show system precision on HPLC [redacted] after maintenance was performed on 07Aug08, is non existent. Suitability of the instrument can not be verified before proceeding with sample analyses. This HPLC is used for Metoprolol analyses.

OBSERVATION 30

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically, data obtained during visual examination of retain samples performed on 04Dec2008 for Hydromorphone HCl 2 mg Tablets lot #'s 94184, 94186, 94188, 94190, 94191 and 95532, were not recorded in a laboratory notebook at the time analysis was performed.

MATERIALS SYSTEM

OBSERVATION 31

There is a lack of rotation so that the oldest approved stock of components is used first.

a. The use of Metoprolol ER pellets 25 mg (approximately (b) (4) per batch) is not performed in sequential order. Batches of ER pellets are consistently used across multiple batches of Metoprolol tablets 25 mg (approximately (b) (4) of pellets used per batch depending on the assay value) without exhausting one batch before using the subsequent batch. The most prevalent example of this practice is demonstrated with (b) (4) batches of Metoprolol ER pellets 25 mg assayed at values below the desirable target of (b) (4) used in manufacture of approximately (b) (4) lots of Metoprolol ER 25 mg Tablets from August to November 2008. This was done with no formal justification.

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CITY, STATE, ZIP CODE, (C)... TRY
Saint Louis, MO 63146-3411

TYPE ESTABLISHMENT INSPECTED
Human Drug Manufacturer

ER Pellets lot#	Release Date	Expiration Date	Assay (mg/g)	Date Used	Quantity Used (kg)	Bulk Tablet	Packaged Lot#
96671	7/8/2008	12/31/2008	(b) (4)	7/30/2008	(b) (4)	98564	98919
				7/31/2008		98503	98871
				8/5/2008		98505	98921
				8/4/2008		98509	Rejected
96855	7/2/2008	12/31/2008	[redacted]	8/5/2008	(b) (4)	98505	Rejected
				8/4/2008		98507	Rejected
				8/4/2008		98508	Rejected
				11/15/2008		100769	96474
96856	8/11/2008	12/31/2008	(b) (4)	8/5/2008	(b) (4)	98504	98872
				10/31/2008		98535	101587
				10/31/2008		99235	101599
				10/10/2008		100544	ECIV Inventory
96857	7/8/2008	12/31/2008	[redacted]	8/10/2008	(b) (4)	98523	99683
				10/8/2008		100540	95905
				10/8/2008		100541	95906
				10/9/2008		100542	100927
				10/10/2008		100543	100928
96858	7/8/2008	12/31/2008	(b) (4)	8/5/2008	(b) (4)	98505	95921
				8/4/2008		98510	Rejected
				11/1/2008		100758	101591
				11/3/2008		100762	101595
				11/15/2008		100769	96474
96859	7/9/2008	12/31/2008	[redacted]	10/28/2008	(b) (4)	98533	101588
				10/27/2008		98534	101589
				10/10/2008		100545	101581
				10/13/2008		100546	101582
				10/14/2008		100547	101583&101585
96860	7/10/2008	12/31/2008	[redacted]	10/30/2008	(b) (4)	99242	95908
				11/3/2008		100759	101592
				11/3/2008		100760	101593
				11/3/2008		100761	101594

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Additionally, of the above lots of Metoprolol Tablets 25 mg using ER pellets of lower potency, none have been placed on stability.

b. **The use of (b) (4) (approximately (b) (4) per batch) is not performed in sequential order. (b) (4) is consistently** used across multiple batches of Metoprolol ER pellets, 25 mg (approximately (b) (4) used per batch) without exhausting one lot before using subsequent batches. The most prevalent example of this practice is demonstrated with batch # 121415 of (b) (4) being used in conjunction with batch # 122572, received approximately three months later. It was used in approximately (b) batches of Metoprolol ER pellets. There were (b) other batches of (b) (4) received between these (b) batches. This was done with no formal justification.

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(b) (4) lot#	Received Date	Expiration Date	Assay (ppm)	ER Pellet lot #	Date Used	Amount Used (kg)
122572	8/20/2008	17000.0000	(b) (4)	98950	11/26/2008	(b) (4)
				98951	11/24/2008	
				98952	11/24/2008	
				98953	11/26/2008	
				98954	11/24/2008	
				101203	11/24/2008	
				101204	11/24/2008	
				101205	11/25/2008	
				101206	11/25/2008	
				101207	11/25/2008	
				101208	11/25/2008	
				101209	11/25/2008	
				101210	11/25/2008	
				101211	11/25/2008	
				101212	11/25/2008	
				101213	11/25/2008	
				101214	11/26/2008	
				101215	12/19/2008	
				101216	12/19/2008	
				101217	12/19/2008	
				101218	12/19/2008	
				101219	1/2/2009	
				101220	1/2/2009	
				101221	1/2/2009	
				101222	1/2/2009	
				101223	1/2/2009	
121415	5/7/2008	17000.0000	(b) (4)	98950	11/26/2008	(b) (4)
				98951	11/24/2008	
				98952	11/24/2009	
				98953	11/26/2008	
				98954	11/24/2008	
				101203	11/24/2008	
				101204	11/24/2008	
				101205	11/25/2008	
				101206	11/25/2008	
				101207	11/25/2008	
				101208	11/25/2008	
				101209	11/25/2008	
				101210	11/25/2008	
				101211	11/25/2008	
				101212	11/25/2008	
				101213	11/25/2008	
				101214	11/26/2008	

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c. Bulk batch 98794 of Hydromorphone was manufactured using (b) (4) lots of Hydromorphone API, lot number 00119768 and 00122132. Lot 0019768 was received prior to receipt of lot no. 00122132. The firm has in stock a total of (b) (4) of Hydromorphone lot 00122132 received 11Jul2008 and 0.455 kg of Hydromorphone lot 0119768 which was received 11Dec2007. Instead of exhausting the entire first in lot of Hydromorphone lot 00119768 a decision was made to use 00122132 received 11Jul2008 first, without justification.

OBSERVATION 32

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, the manner in which the water samples are collected does not allow you to determine the actual quality of the water.

QA/QC sampling and testing of water from the closed loop, continuously circulated purified USP water system (SOP 211.84.01 "Sampling, Testing, and Approval of Purified Water USP, Deionized Water, and Potable Water") is not performed at a minimum of (b) (4) nor performed at a frequency to encompass worse case testing. Sampling is not performed more frequently on water ports which have a greater use rate, and sampling is not organized to ensure it is representative of true use scenarios when sampling occasionally occurs post sanitization. SOP 211.84.01 section 7.2.6.2.2 states (b) (4) [redacted]

- Port (b) (4) **No sampling is documented in the point of use log from 3Oct2008 through 29Nov2008; nearly a two month time span.**
- Port (b) (4) No sampling is documented in the point of use log encompassing the dates from 27Oct2008 until 1Dec2008, which is **outside the time of** (b) (4) **as specified in the SOP. Additionally, a sample was collected** (b) (4) **after hose sanitization with no production use documented between those points.**
- Port (b) (4) Sampling occurred on 27Oct2008 as documented in the point of use log. Sampling failed to occur again until 8Dec2008 and **was not documented again, showing sampling** (b) (4) **during a 2 month time span.**

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PRODUCTION SYSTEM

OBSERVATION 33

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

a. **You failed to follow your procedure, 211.68.343, "Assignment and Control of Passwords and Recipes Used for** Production Equipment," in which no change documentation was submitted for numerous updated recipe versions. This procedure requires that a (b) (4) [redacted]

The procedure also requires the (b) (4) [redacted] NCR #16175 was initiated 31Aug2008 for lack of training a[redacted] formal program to ensure compliance wi[redacted] procedure. CAPA #16175 was initiated 14Nov2008 to implement a program to ensure compliance. However, to date, the program has not been fully implemented. (b) (4) [redacted] For example (b) (4) [redacted] for Hydromorphone HCl Tablets, 2 mg is currently on version (b) (4) [redacted] there is no log documenting these changes or copies of the (b) (4) [redacted] available for review. Additionally, CME, Press Technician has not been trained regarding this procedure. (4)

b. You failed to justify the deletion of (b) (4) [redacted] testing in the master production record (MPR) for Potassium Chloride Extended-Release Granules (VPCL-2C) with the proper change control documentation. Review of the MPR history for this product found the following description added to revision [redacted] This revision reads in part (b) (4) [redacted] The reason for the revision listed in the MPR is (b) (4) [redacted] However, during the review of the most recent revision to the MPR (revision [redacted] the required test wasn't present and hadn't been present since revision [redacted] The history does not indicate this test was removed, nor does it give a justification for its deletion.

c. You failed to follow your SOP 211.100.94-03 "Change Control" for Change Initiation Form CIF-0007492 for the revision of Potassium Chloride ER Capsule 750 mg method no. 5128.19. Review of the redline document for this method finds Proven Acceptable Range (PAR) specifications were added to the method for the timed release test and states in part (b) (4) [redacted]

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(b) (4) specifications. These are shown below. (b) (4) (b) (4) The (b) (4) specifications are listed in the method and are outside the specifications in LIMS.

The Change Control procedure was not followed in that the CIF document under (b) (4) and (b) (4) does not describe the (b) (4) and the justification for the use of this specification by the analysts.

d. You failed to follow procedure 1300.05-04 which in section 7.6.2 states, (b) (4) (b) (4) (b) (4) The drum will be (b) (4) (b) (4) Upon inspection of the controlled substance vault, (b) (4) (b) (4) numerous containers were found unsealed and in some cases polyplastic bags were the only containment of controlled substances such as Morphine and Oxycodone drug products. In this same procedure in section 7.7.2.1 it states, (b) (4) It was observed that waste had spilled out of unsealed plastic bags and were not contained in the typical fiber drums.

e. Master Production Records (MPRs) for bulk Morphine Sulfate 30 & 60 mg ER Tablets are deficient in that;

- There are no in-process time limits for the time between date of manufacture and the end of the processing of the tablets
- There are two different (b) (4) codes listed for one granulation process
- The 60 mg MPR incorrectly directs omitting of the milling step.

OBSERVATION 34

All processing lines used during the production of a batch of drug product is not properly identified at all times to indicate the phase of processing of the batch.

Specifically, the cleaning and use log for bay number [redacted] and (b) (4) did not agree with the in-process batch number listed on the placard at the entrance to Bay [redacted]. According to the cleaning and use logs, Oxycodone 30 mg, lot # 98705 was to be manufactured and approved on 16Dec2008. However, the placard indicated Oxycodone 30 mg, lot # 98706 had been approved for use on 16Dec2008. (b) (4)

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OBSERVATION 35

Batch production and control records do not include the identification of the persons performing each significant step in the operation, for each batch of drug product produced.

Specifically, prior to production, maintenance technician [redacted] adjusted press parameters on the PLC and checked tablet characteristics for Hydromorphone 2 mg lot number 94184. However, he did not sign the batch production record as having participated in the batch preparation.

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Exhibit 3

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No.
KV PHARMACEUTICAL COMPANY,	)	
ETHEX CORPORATION, and	)	
THER-RX CORPORATION,	)	
corporations, and	)	
DAVID A. VAN VLIET,	)	
MARC S. HERMELIN,	)	
RITA E. BLESER, and	)	
JAY S. SAWARDEKER,	)	
individuals,	)	
	)	
Defendants.	)	

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction ("Complaint") against KV Pharmaceutical Company, a corporation with corporate offices located at 2503 South Hanley Road, St. Louis, Missouri and drug manufacturing facilities located at various locations in St. Louis, Missouri; ETHEX Corporation, a corporation with offices located at 1 Corporate Woods Drive, St. Louis, Missouri; and Ther-Rx Corporation, a corporation with offices located at 1 Corporate Woods Drive, St. Louis, Missouri (hereafter, collectively, "KV"); and David A. Van Vliet, Interim Chief Executive Officer of KV Pharmaceutical (who assumed that position on December 5, 2008); Marc S. Hermelin, former Chief Executive Officer of KV Pharmaceutical Company (holding

that position from 1975 to December 5, 2008) and current member of the Board of Directors for KV Pharmaceutical; Rita E. Bleser, President/Pharmaceutical Division of KV Pharmaceutical; and Jay S. Sawardeker, Vice President, Corporate Quality Assurance/Quality Control of KV Pharmaceutical, individuals (hereafter, collectively, "Defendants"), and Defendants while disclaiming any liability in connection therewith, having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, solely for the purpose of settling this case, and without admitting or denying the allegations in the Complaint, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. § 1345.

2. Venue is proper in this District under 28 U.S.C. §§ 1391(b)-(c) and 1395.

3. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 ("the Act"), and alleges:

A. Defendants violate 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1) (hereinafter, "drug" or "drugs"), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of current good manufacturing practice ("CGMP") requirements, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants violate 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug after shipment of one or more of their components in interstate commerce;

C. Defendants violate 21 U.S.C. § 331(d), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

D. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Defendants violate 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

4. Except as provided otherwise in this paragraph, within forty-five (45) calendar days of entry of this Decree, Defendants shall, under the supervision of the United States Food and Drug Administration's ("FDA" or the "agency"), destroy: (1) all drugs in Defendants' possession, custody, and/or control that are the subject of recalls announced by KV from May 2008 through February 3, 2009; and (2) all other drugs in Defendant's possession, custody, and/or control, including all in-process drugs and drug components, as well as finished drugs. This paragraph does not, however, apply to raw materials that either have never been opened by Defendants or that have been opened by Defendants for the limited purpose of quality control sampling. With respect to any additional recalled or returned KV drugs that subsequently come

into Defendants' possession, custody, and/or control, Defendants shall quarantine any such products, notify FDA in writing of their receipt, and destroy any such products, under FDA's supervision, no later than thirty (30) calendar days after their receipt. Recalled drug products that are the subject of pending or threatened litigation ("litigation hold drugs"), however, may be preserved in limited quantities for evidentiary purposes only, for so long as that need exists, but shall be destroyed under FDA's supervision when that need no longer exists. Defendants will isolate and maintain the litigation hold drugs in a manner that ensures that any such drugs in their possession, custody, and/or control are not introduced into commerce. Within thirty (30) calendar days of receipt of a reasonably detailed bill of costs, Defendant KV shall reimburse FDA for the supervision of any destruction under this paragraph, at the rates set forth in paragraph 10 of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state; or local laws, including but not limited to, the National Environmental Policy Act of 1969.

5. Upon entry of this Decree, Defendants and each and all of their subsidiaries, directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly, doing or causing: the manufacture, processing, packing, labeling, holding, introduction or delivery for introduction into interstate commerce at or from any of the KV facilities, of any drug, as defined by 21 U.S.C. § 321(g)(1), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with CGMP, 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211; and

B. Defendants establish and document management control over Quality Assurance ("QA") and Quality Control ("QC") for all KV facilities, including but not limited to Research and Development facilities and production facilities to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for QA and QC shall be vested in an individual who shall be authorized and responsible for all QA and QC functions at all KV facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA and QC program ("QA/QC program") to ensure that all drug products manufactured, processed, packed, held, and distributed by KV have the safety, identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the provisions of this Decree; and

C. Defendants establish and follow scientific product development and manufacturing process design procedures at all KV facilities to control all significant variables (including material attributes and processing parameters) affecting in-process material and final drug product specifications and quality attributes; and

D. Defendants retain, at Defendant KV's expense, an independent person or persons (the "CGMP expert"), who has no personal or financial relationship (other than the consulting agreement between the parties), with Defendants or their immediate families, and who by reason of background, training, education, and experience, is qualified to inspect Defendants' drug manufacturing facilities to determine whether the methods, facilities, and controls are operated

and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert; and

E. Defendants shall submit a protocol that identifies the work plan for the CGMP expert and the methodology that will be used by the CGMP expert (the "work plan") to ensure that KV's corrective actions are implemented and that the manufacturing, processing, packing, labeling, holding, and distribution of drugs is operated and will be continuously administered in conformity with CGMP. Defendants shall first obtain FDA's written approval of the work plan prior to the CGMP expert performing his or her inspection as set forth in paragraph 5(F)-(H); and

F. The CGMP expert shall perform a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The CGMP expert shall determine whether Defendants' facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with CGMP; and

G. The CGMP expert shall evaluate whether Defendants have established and implemented a comprehensive written QA/QC program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The CGMP Expert, at a minimum, shall determine whether the QA/QC program:

(1) Addresses all facets of compliance monitoring and trend analyses; records management systems for those records that relate to the safety, identity, strength, quality, and purity of in-process, bulk, and finished product and internal audit procedures, and confirms that Defendants' Quality Control Unit, as defined by 21 C.F.R. § 210.3(b)(15), is sufficiently trained

to evaluate CGMP compliance on an on-going basis and to prevent and correct any future deviations from CGMP;

(2) Includes procedures to ensure that Defendants, in a timely manner, thoroughly investigate product deviations, reports of complaints regarding the use of KV's products, and any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy, and to take required and timely corrective actions for all products and components that fail to meet their specifications;

(3) Includes procedures to ensure that Defendants, in a timely manner, thoroughly investigate any returns or complaints regarding the use of KV's products, and any associated trends, and take any needed corrective action(s) in a timely manner;

(4) Establishes mechanisms to ensure that written standard operating procedures ("SOPs") are periodically re-evaluated so that they remain in continuous compliance with CGMP, and that the SOPs address all facets of CGMP and are reviewed and controlled by an independent QA unit;

(5) Includes written SOPs to ensure that: (i) KV's division level QA personnel are notified in writing of deviations and/or problems that could affect the safety, identity, strength, quality and purity of any drug, (ii) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems, and (iii) there are systems to ensure that such written SOPs are continuously followed; and

(6) Includes written SOPs specifying the responsibilities and procedures applicable to QA or QC personnel and that establishes mechanisms to ensure such SOPs are followed; and

H. The CGMP expert certifies in writing to FDA that:

(1) He or she has inspected Defendants' facilities, methods, processes, and controls;

(2) All the requirements of paragraph G have been met;

(3) That all CGMP deviations brought to Defendants' attention since January 1, 2005, by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected;

(4) Such facilities, methods, processes, and controls are in compliance with the requirements of CGMP; and

(5) As part of this certification, the CGMP expert shall include a complete and detailed report of the results of his or her inspection; and

I. Defendants submit to FDA for approval a written batch certification protocol ("certification protocol"), and shall not commence batch certification until FDA has first approved the certification protocol in writing. Upon FDA's written approval of the certification protocol, Defendants' CGMP expert shall certify in writing that the first three (3) consecutive batches of each product meet the requirements of the certification protocol; and

J. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by FDA since January 1, 2005, the CGMP expert, and any other source including, but not limited to, any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP.

Defendants may submit two (2) interim reports under this subparagraph 5(J), which shall include the CGMP drug expert certification described in subparagraph 5(H)(1),(2),(4), and (5), in support of requests to begin marketing a particular product(s); and

K. Within twenty (20) calendar days of receipt of Defendants' report(s) under paragraph 5(J), FDA may, in its discretion and without prior notice, commence an inspection of Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, its implementing regulations, and this Decree; and

L. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraph 4 above and in subparagraphs 5(A)-(K), which notification shall be issued no later than twenty (20) calendar days after conclusion of any inspection, or, if FDA does not inspect Defendant KV's facilities, within twenty (20) calendar days of receiving Defendants' report under paragraph 5(J). In no circumstance may FDA's silence be construed as a substitute for written notification.

M. Nothing in paragraph 5 shall preclude Defendants from manufacturing, processing, packing, and holding drug products for the sole purpose of performing equipment qualification, validation of drug manufacturing processes, method validation, or stability studies. Defendants shall maintain in a separate file at the KV facility a written log of all lot numbers of drugs manufactured under this provision, and shall promptly make such log available to FDA

upon request. None of the drugs produced under subparagraph 5(M) may be distributed.

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons or entities in active concert or participation with any of them (including franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing the drugs identified in Appendix A (attached hereto) or any other drug that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until:

(1) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug;

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations, and the use and distribution of such drug conforms strictly with the investigational new drug application; or

(3) in the event Defendants decide to make or distribute a dietary supplement, they shall notify FDA in writing sixty (60) calendar days before any such manufacture or distribution and shall retain, at Defendant KV's expense, an independent person or persons (the "dietary supplement expert"), without a personal or financial relationship (other than the consulting agreement between the parties) with Defendants or their immediate families, and who by reason

of background, experience, education, and training, is qualified to inspect Defendants' facilities, product formulation and labeling, including promotional material and internet site information, for all drugs and dietary supplements manufactured, stored, processed, labeled, packed, or distributed by Defendants. Defendants shall notify FDA in writing of the identity of the dietary supplement expert as soon as they retain such person.

(a) The dietary supplement expert shall perform a comprehensive inspection of Defendants' facilities, product formulation and labeling, including promotional material and internet site information. The dietary supplement expert shall determine whether Defendants have eliminated all drug claims from their labeling, including promotional materials and internet information.

(b) Defendants' dietary supplement expert shall certify in writing to FDA that he or she has inspected Defendants' facilities, product formulation and labeling, including promotional material and internet site information, that Defendants are not making drug claims for any of their products, and that such products are properly formulated and constitute lawful dietary supplements, within the meaning of 21 U.S.C. § 321(ff). As a part of this certification, the dietary supplement expert shall include a complete and detailed report of the results of his or her inspection;

(c) Defendants shall report to FDA in writing the actions they have taken to correct product formulation and eliminate all drug claims from their labeling, including any promotional materials and internet site information. Defendants may submit two (2) interim reports under this subparagraph, which shall include the dietary supplement expert certification described in subparagraph 6(b), in support of requests to begin marketing of a particular product(s);

(d) Within forty-five (45) calendar days after receiving a report under subparagraph 6(c), FDA shall either notify Defendants in writing that, with respect to the products identified in the report as having been reviewed, (1) the product(s) appear to be compliance with the requirements of this Decree and the Act, or (2) the product(s) do not appear to be in compliance with the requirements of this Decree and the Act. Any FDA notification under subparagraph 6 (d)(2) shall be accompanied by a written statement of the reasons for such noncompliance.

B. Nothing in paragraph 6(A) shall preclude Defendants from:

1. Manufacturing, processing, packing, or holding drug products for non-clinical laboratory studies or other research and testing that does not involve exposure of human research subjects or bioequivalence testing. None of the drugs produced under this subparagraph may be distributed; or

2. Manufacturing processing, packing, holding, and distributing a drug product intended for export that meets the requirements of 21 U.S.C. § 381 and § 382 to FDA's satisfaction;

C. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); or any dietary supplement that is adulterated within the meaning of 21 U.S.C. § 402(g)(1);

D. Causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug or any of its components are held for sale after shipment of one or more components in interstate commerce; and

E. Causing the adulteration of any dietary supplement within the meaning of 21 U.S.C. § 402(g)(1), while such dietary supplement is held for sale after shipment of one or more components in interstate commerce.

7. Nothing in this Decree shall prohibit Defendant from distributing any FDA-approved drug products or products not requiring approval under the Act that are manufactured, processed, packed, labeled, held, or distributed at or by a third party or parties, so long as Defendants perform no manufacturing, processing, packing, or labeling functions with respect to such drugs, and Defendants' sole responsibility is that of a distributor.

8. After Defendants have complied with paragraphs 4-5 and FDA has provided the notifications pursuant to paragraph 5(L), Defendants shall retain an independent person or persons (the "auditor") to conduct audit inspections of KV's drug manufacturing operations no less frequently than once every six (6) months for a period of no less than two (2) years and annually thereafter for an additional period of three (3) years. The auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) with any of KV's officers or employees or their immediate families and may, if KV chooses, be the same person or persons described as the CGMP expert and/or dietary supplement expert, as set forth in paragraphs 4-5; and

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendant KV is in compliance with the Act, its implementing regulations, and this Decree, and identifying in detail any deviations therefrom ("audit report observations"). As a part of every audit report, except the first audit

report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection(s) is completed. If audit reports identify deviations from the Act, its implementing regulations, or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request;

B. If an audit report contains any adverse observations, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the audit report observations will take longer than thirty (30) calendar days, Defendants shall, within fifteen (15) business days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule") and provide a justification describing why the additional time is necessary. Before becoming effective, the correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. FDA shall respond to the proposed correction schedule within fifteen (15) business days of receiving it. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions

taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected; and

C. In addition to the foregoing audit reports, Defendants' Auditor shall, with respect to each product that has been approved by FDA for distribution following the successful completion of batch certification described in paragraph 5(I) and resumption of manufacture and distribution under paragraph 5(L), report in writing to FDA on a quarterly basis, beginning with the date of entry of this Decree, whether the succeeding batches of such product(s) meet the protocol certification requirements.

9. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' places of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to Defendants' places of business including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drugs, including components thereof, in order to ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate

credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. Defendant KV shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendant KV at the standard rates in effect at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $85.49 per hour or fraction thereof per representative for inspection and investigative work; $102.49 per hour or fraction thereof per representative for laboratory and analytical work; $0.55 per mile for travel expenses by automobile; the government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

11. Within ten (10) business days of the date of entry of this Decree, Defendants shall provide a copy of the Decree, by personal service, personal delivery via electronic mail ("email") with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested), to each and all of the following "Associated Persons": (i) employees, directors, officers, agents, representatives, attorneys, successors, and assigns of KV, and any and all persons or entities in active concert or participation with any of them, including, but not limited to, all parties for whom KV contract manufactures products and own label distributors with whom KV is affiliated, and all others involved in the manufacture or quality of KV's products. In the event that Defendants become associated, at any time after the entry of this Decree, with new

Associated Persons, Defendants shall within fifteen (15) calendar days of such association, (a) provide a copy of this Decree to such person(s) by personal service, personal delivery via email with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested) and (b) shall furnish FDA with an affidavit of compliance (signed by a person with personal knowledge of the facts) identifying the names, addresses, and positions of all new Associated Persons that received a copy of the Decree. Within twenty (20) calendar days of the date of entry of this Decree, Defendants shall provide a copy of this Decree to all of Defendants' employees involved in the manufacture, processing, packing, storage, or distribution of drugs at Defendant KV's facilities and shall post a copy of this Decree in the employee common areas at all facilities where such employees are located. Defendants shall ensure that the Decree remains posted in the employee common areas for no less than twelve (12) months. Within thirty (30) calendar days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit (signed by a person with personal knowledge of the facts) stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph. Notice provided by electronic mail, as specified above, shall be adequate to satisfy the requirements of Federal Rule of Civil Procedure 65(d)(2).

12. Defendant KV shall notify FDA, in writing at least fifteen (15) calendar days before any change in ownership, character, or name of any of its businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the structure or identity of

Defendant KV (or any of any of its parents or subsidiaries), or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assignee at least thirty (30) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than fifteen (15) business days prior to such assignment or change in ownership.

13. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP expert, the dietary supplement expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate corrective actions, including, but not limited to, the following:

A. Cease all manufacturing, processing, packing, repacking, labeling, holding, and/or distributing any or all drug(s) and dietary supplements;

B. Recall, at Defendant KV's expense, any drug or dietary supplement manufactured, processed, packaged, labeled, held, or distributed by Defendant KV that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a safety alert with respect to a drug or dietary supplement manufactured, processed, packaged, labeled, held, or distributed by Defendant KV; and/or

F. Take any other corrective actions with respect to any drug or dietary supplement manufactured, processed, packaged, labeled, held, or distributed by Defendant KV as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

Any FDA order issued pursuant to this paragraph shall specify the noncompliance giving rise to the order.

14. The following process and procedures shall apply when FDA issues an order under paragraph 13:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, it shall explain the basis

for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. The Court's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 19.

D. The process and procedures set forth in Paragraphs 14(A)-(C) shall not apply to any order issued pursuant to paragraph 13 if such order states that, in FDA's judgment, the order must be implemented immediately. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they shall begin compliance with the order while they petition this Court for relief.

15. Any cessation of operations or other action described in paragraphs 13-14 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may, therefore, resume operations. Upon Defendants' written request to resume operations, FDA shall endeavor to determine within forty-five (45) calendar days of receipt of the request whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting resumption of operations. The costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, sampling, testing, travel time, and subsistence expenses to

implement the remedies set forth in this paragraph and paragraphs 13-14, shall be borne by Defendant KV at the rates specified in paragraph 10 of this Decree.

16. The parties may at any time petition each other in writing to extend any deadline provided for herein; and, if the parties mutually agree to extend a deadline, such extension may be granted without seeking leave of Court.

17. Defendant David A. Van Vliet shall notify FDA in writing if, at any time after entry of this Decree, he ceases to be employed by or affiliated in any way with Defendant KV and shall provide FDA with supporting documents showing that he is no longer employed by Defendant KV and identifying his new employer. Defendant Van Vliet may, after providing FDA with thirty (30) calendar days written notice, petition the Court to be released from this Decree. Unless, within such 30-day period FDA determines that Defendant Van Vliet has not ceased to be employed by or affiliated with Defendant KV, FDA will not oppose the release of such individual, from this Decree pursuant to such petition.

18. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendant KV shall pay to the United States of America: fifteen thousand dollars ($15,000.00) in liquidated damages for each day such violation continues, and an additional sum of fifteen thousand dollars ($15,000.00) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree. The amount of liquidated damages imposed under this paragraph shall not exceed five million dollars ($5,000,000) in any calendar year. In addition, should Defendants distribute any unapproved new drug(s), Defendant KV shall, in addition to the foregoing, also pay to the United States as liquidated damages a sum equal to

three times the retail value of such drug(s). Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the power of the Court to impose, additional criminal or civil penalties to be paid by Defendant KV, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

19. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A) and shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

20. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to the District Director, FDA Kansas City District Office, 11630 W. 80th St., Lenexa, KS, 66214-3340. All notifications, correspondence, and communications required to be sent to KV by the terms of this Decree shall be marked "Consent Decree Correspondence" and shall be addressed to the General Counsel, KV Pharmaceutical Company, 1 Corporate Woods Drive, St. Louis, Missouri 63044.

21. If Defendants have maintained at Defendants' facilities a state of continuous compliance with this Decree, the Act, and all applicable laws and regulations for a period of six (6) years after satisfying all of their obligations under paragraph 5, Defendants may petition this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment Defendants have met the foregoing criterion, Plaintiff will not oppose such petition.

22. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendant KV shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses as specified in paragraph 10, and court costs relating to such contempt proceedings.

23. This Decree resolves only those claims set forth in the Complaint in this action, and does not affect any other civil, criminal, or administrative claims that the government may have or bring in the future against the Defendants herein.

24. Notwithstanding the foregoing, the provisions of this Decree, other than this paragraph, shall not apply to Defendant Marc S. Hermelin so long as: (1) the December 5, 2008, Resolutions of the KV Pharmaceutical's Board of Directors terminating his employment agreement and his employment remain in full force and effect with respect to his employment with Defendant KV, and (2) Defendant Marc S. Hermelin has no role in the decisionmaking, management, or operation of the Defendant KV that could affect the company's compliance with the Act, its implementing regulations, or this Decree. In the event the referenced resolutions should in any way be changed with respect to his employment with Defendant KV or should Marc S. Hermelin assume any role in the decisionmaking, management, or operation of KV that could affect the company's compliance with the Act, its implementing regulations, or this Decree, then all the provisions of this Decree immediately apply with full force and effect to Defendant Marc S. Hermelin. Nothing in this paragraph shall be construed to prejudice Defendant Marc S. Hermelin's right to contest the grounds on which he was terminated or to seek recovery of payments to which he may be due. Nothing in this paragraph shall prevent any Defendant from

suing any other Defendant or reflect on the merits of any such suit.

25. This Decree states the complete understanding and agreement of the parties and shall be interpreted by the Court within its four corners, without consideration of any alleged collateral agreements. Any changes or modifications to the Decree must be in writing and signed by all parties and entered by the Court.

26. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this ___ day of _____, 2009.

_____
UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

DAVID A. VAN VLIET
Individually and on behalf
of KV Pharmaceutical
as its Chief Executive Officer

MARC S. HERMELIN
Individually

RITA E. BLESER
Individually

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Appendix A
KV's List of Unapproved Drug Products

Drug Name	Active Ingredients
Advanced NatalCare Tablets	Vitamin A (beta-carotene) ...2700 I.U. Vitamin C (ascorbic acid)....120 mg Vitamin D_3 (cholecalciferol)...400 IU. Vitamin E (dl-alpha-tocopheryl acetate) ...30 I.U. Vitamin B_1 (thiamine momonitrate, USP).....3 mg Vitamin B_2 (riboflavin, USP)....3.4mg Niacin (niacinamide).....20 mg Vitamin B_6 (pyridoxine hydrochloride, USP) .....20 mg Folic Acid, USP.....1 mg Vitamin B_{12} (cyanocobalamin)...12 mcg Calcium (calcium carbonate)...200 mg Iron, elemental (carbonyl iron) ....90 mg Magnesium (magnesium oxide, USP)...30 mg Zinc (zinc oxide, USP).....25 mg Copper (cupric oxide).....2 mg Docusate Sodium ....50 mg
Advanced-RF NatalCare Tablets & Capsules	Vitamin C (ascorbic acid)....120 mg Vitamin D_3 (cholecalciferol)...400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) ...30 I.U. Vitamin B_1 (thiamine momonitrate, USP).....3 mg Vitamin B_2 (riboflavin)....3.4mg Niacin (niacinamide).....20 mg Vitamin B_6 (pyridoxine hydrochloride) .....20 mg Folic Acid.....1 mg Vitamin B_{12} (cyanocobalamin)...12 mcg Calcium (calcium carbonate)...200 mg Elemental Iron (carbonyl iron) ....90 mg Magnesium (magnesium oxide)...30 mg Zinc (zinc oxide).....25 mg Copper (cupric oxide).....2 mg Docusate Sodium ....50 mg
Cal-Nate Tablets	Vitamin C (ascorbic acid)....120 mg Vitamin D_3 (cholecalciferol)...400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) ...30 I.U. Vitamin B_1 (thiamine momonitrate, USP).....3 mg Vitamin B_2 (riboflavin)....3.4mg Niacin (niacinamide).....20 mg Vitamin B_6 (pyridoxine hydrochloride) .....20 mg Folic Acid.....1 mg

Drug Name	Active Ingredients
	Calcium (calcium carbonate)…125 mg Iron (carbonyl iron, ferrous gluconaye) ….27 mg Iodine (potassium iodide) ……150 mcg Zinc (zinc oxide, USP) ….25 mg Copper (cupric oxide) …..2 mg Docusate Sodium ….50 mg
CareNatal DHA Tablets & Capsules	Vitamin A (100% as beta carotene)…3000 IU Vitamin C (ascorbic acid)…120 mg Vitamin D_3 (cholecalciferol)…400 IU Vitamin E (kl-alpha-tocopheryl acetate)…30 mg Vitamin B_1 (thiamine mononitrate)…1.8 mg Vitamin B_2 (riboflavin)…4 mg Niacin (niacinamide)…20 mg Vitamin B_6 (pyridoxine hydrochloride)…25 mg Folic Acid….1 mg Vitamin B_{12} (cyanocbalamin)…12 mcg Calcium (calcium carbonate)…200 mg Iron (Ferrochel and iron protein succinylate)…29 mg Magnesium (magnesium oxide)…25 mg Zinc (zinc oxide) ….25 mg Copper (cupric oxide)…2 mg
Chromagen Caplets (Ther-Rx) **Anemagen Caplets (ETHEX)**	Iron (as Sumulate elemental iron) 70mg, Succinic Acid 75mg, Ascorbic acid (as calcium ascorbate 150mg), Threonic acid (as calcium threonate 2 mg), Vitamin B12 10mcg, Desiccated stomach substance 50mg
Chromagen FA Caplets	Iron (as Sumulate elemental iron) 70mg, Succinic Acid 75mg, Ascorbic acid (as calcium ascorbate 150mg), Threonic acid (as calcium threonate 2 mg), Vitamin B12 10mcg, Folic Acid 1 mg
Chromagen Forte Caplets (Ther-Rx) **Anemagen Forte Caplets (ETEX)**	Iron (sumalate 50 mg, Ferrous fumarate 101mg), succinic acid 50 mg, Ascorbic acid (as calcium ascorbate 60 mg), Threonic acid (as calcium threonate 0.8 mg), Folic Acid, USP 1 mg, Vitamin B12 10 mcg
Codeine Phosphate & Guaifenesin Tablets	Codeine phosphate…10 mg Guaifenesin ….300 mg
ComBgen Tablets	Folic Acid … 2.2 mg Vitamin B_6 ….25 mg Vitamin $B1_2$ ….500 mcg
ComBiRx Tablets (ETHEX) **Premesis Rx (Ther-Rx)**	Vitamin B_6 (pyridoxine hydrochloride, USP) …..75 mg Folic Acid, USP……..1 mg Vitamin B_{12} (cyanocobalamin)…….. 12 mcg Calcium (calcium carbonate)…….. 200 mg
Conison Capsules	Special liver-stomach concentrate (containing intrinsic factor)

Drug Name	Active Ingredients
	...240 mg Vitamin B_{12} (activity equivalent) .....15 mcg Iron, elemental (ferrous fumarate) ...110 mg Vitamin C (ascorbic acid) ...75 mg Folic acid ...0.5
Encora Tablets and Capsules	AM tablet – Calcium (calcium carbonate) 400mg, Vitamin D3 200 IU, Vitamin C (ester C) 25mg, Folic Acid USP 2 mg, Vitamin B6 25 mg. PM tablet – Calcium (calcium carbonate) 600 mg, Vitamin D3 600 IU, Vitamin C (ester C) 25mg, Folic Acid USP 0.5 mg, Vitamin B6 12.5 mg. AM and PM capsule – DHA and EPA 550 mg, Lenolenic Acid (ALA) 100 mg, Linoleic Acid (LA) 10mg, Vitamin E 50 IU.
EtheDent Brush-On Gel	Sodium Fluoride 1.1% (w/v)
EtheDent Chewable Tablets	1 mg fluoride ion (F^-) from 2.2 mg sodium fluoride (NaF). 0.5 mg F tablet (half-strength) contains 05. mg F^- from 1.1 mg NaF. 0.25 mg F table (quarter-strenght) contains 0.25 mg F^- from 0.55 mg NaF.
EtheDent Dental Cream	Sodium Fluoride 1.1% (w/v)
EthexDERM BPW-5 and BPW -10	Benzoyl peroxide 5% and 10%
ETH-Oxydose (Oral Oxycodone HCl) Concentrate Solution, CII	Oxycodone HCl, 20mg/1 mL
ETH-Oxydose (Oxycodone HCl) Oral Concentrate Solution InvaAmp Unit Dose Ampoules, CII	Oxycodone HCl, 20mg/1mL
Hydrocortisone and Iodoquinol 1% Cream	Hydrocortisone 10 mg/gm (1%) Iodoquinol 10 mg/gm (1%)
Hyoscyamine Sulfate Extended-Release Capsules	Hyoscyamine sulfate 0.375 mg
Hyoscyamine Sulfate Extended-Release Tablets	Hyoscyamine Sulfate 0.375
Hyoscyamine Sulfate Oral	Hyoscyamine sulfate 0.125 mg

Drug Name	Active Ingredients
Tablets	
Hyoscyamine Sulfate Orally Disintegrating Tablets	Hyoscyamine sulfate 0.125 mg
Morphine Sulfate Concentrated Oral Solution, CII	Morphine Sulfate 20 mg/1 mL Packaged sizes: 15mL, 30mL, 120mL, 240mL
Morphine Sulfate Immediate-Release Tablets, CII	Morphine sulfate 15 mg and 30 mg
NataCaps Capsules	Vitamin C 200 mg Iron (ferrous fumarate) 324 mg (equivalent to about 106 mg of elemental iron) Vitamin B1 (thiamine mononitrate) 10 mg Vitamin B2 (riboflavin) 6 mg Niacinamide 30 mg Vitamin B6 (pyridoxine hydrochloride) 5 mg Folic Acid 1 mg Vitamin B12 (cyanocobalamin concentrate) 15 mcg Pantothenic Acid (calcium pantothenate) 10 mg Copper 0.8 mg Manganese (manganese sulfate) 1.3 mg
NatalCare GlossTabs Tablets	Vitamin A (beta carotene) 2700 I.U. Vitamin C (ascorbic acid) 120 mg Vitamin D3 (cholecalciferol) 400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) 10 I.U. Vitamin B1 (thiamine mononitrate) 3 mg Vitamin B2 (riboflavin) 3.4 mg Niacin (niacinamide) 20 mg Vitamin B6 (pyridoxine hydrochloride) 20 mg Folic Acid 1 mg Biotin 30 mcg Pantothenic Acid (calcium pantothenate) 6 mg Vitamin B12 (cyanocobalamin) 12 mcg Calcium (calcium carbonate) 200 mg Iron, elemental (carbonyl iron) 90 mg Magnesium (magnesium oxide) 30 mg Zinc (zinc oxide) 15 mg Copper (cupric oxide) 2 mg Docusate Sodium 50 mg
NatalCare PIC Forte Tablets	Vitamin A (vitamin A acetate) 5000 I.U. Vitamin C (ascorbic acid) 80 mg

Drug Name	Active Ingredients
	Vitamin E (dl-alpha-tocopheryl acetate) 30 I.U. Vitamin D (cholecalciferol) 400 I.U. Vitamin B1 (thiamine mononitrate) 3.4 mg Vitamin B2 (riboflavin) 3 mg Niacinamide 20 mg Vitamin B6 (pyridoxine hydrochloride) 4 mg Folic Acid 1 mg Vitamin B12 (cyanocobalamin) 12 mcg Calcium (calcium carbonate) 250 mg Iron, elemental (polysaccharide-iron complex) 60 mg Zinc (zinc sulfate monohydrate) 18 mg Iodine (potassium iodide) 0.2 mg Magnesium (magnesium oxide) 10 mg Zinc (zinc sulfate) 25 mg Copper (cupric oxide) 2 mg
NatalCare Plus Tablets	Vitamin A (vitamin A acetate and beta carotene) 4,000 I.U. Vitamin C (ascorbic acid) 120 mg Calcium (calcium sulfate) 200 mg Iron (ferrous fumarate) 27 mg Vitamin D3 (cholecalciferol) 400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) 22 I.U. Vitamin B1 (thiamine mononitrate) 1.84 mg Vitamin B2 (riboflavin) 3 mg Niacinamide 20 mg Vitamin B6 (pyridoxine hydrochloride) 10 mg Folic Acid 1 mg Vitamin B12 (cyanocobalamin) 12 mcg Zinc (zinc oxide) 25 mg Copper (cupric oxide) 2 mg
NataTab Rx Tablets	Vitamin A (beta carotene) 4000 I.U. Vitamin C (ascorbic acid) 120 mg Vitamin D3 (chlolecalciferol) 400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) 30 I.U. Vitamin B1 (thiamine mononitrate) 3 mg Vitamin B2 (riboflavin) 3 mg Niacin (niacinamide) 20 mg Vitamin B6 (pyridoxine hydrochloride) 3 mg Folic Acid 1 mg Vitamin B12 (cyanocobalamin) 8 mcg Biotin 30 mcg Pantothenic Acid 7 mg Calcium (calcium carbonate) 200 mg Iron (carbonyl iron) 29 mg

Drug Name	Active Ingredients
	Iodine (potassium iodide) 150 mcg Zinc (zinc oxide) 15 mg Copper (cupric oxide) 3 mg Magnesium (magnesium oxide) 100 mg
Niferex Gold Tablets	Ferrochel (elemental iron) 50 mg, Polysaccharide iron complex (elemental iron) 150mg, Succinic acid 50 mg, Asorbic acid (as calcium ascorbate 60 mg, Threonic acid (calcium threonate) 0.8 mg, Folic acid USP 1 mg, Vitamin B12 25mcg, Zinc (zinc oxide) 10 mg, Docusate sodium 50 mg
Nitroglycerin Extended-Release Capsules	Nitroglycerin 2.5 mg, 6.5 mg, and 9 mg
NitroQuick Sublingual Tablets, 0.3, 0.4 and 0.6 mg	Nitroglycerin 0.3, 0.4 and 0.6 mg
NutriNate Chewable Tablets	Vitamin A (beta carotene) 1,000 I.U. Vitamin C (sodium ascorbate and ascorbic acid) 120 mg Vitamin D3 (cholecalciferol) 400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) 11 I.U. Vitamin B1 (thiamine mononitrate) 2 mg Vitamin B2 (riboflavin) 3 mg Niacinamide 20 mg Vitamin B6 (pyridoxine hydrochloride) 10 mg Folic Acid 1 mg Vitamin B12 (cyanocobalamin) 12 mcg Iron (ferrous fumarate) 29 mg
NutriSpire Tablets	Vitamin C (ascorbic acid) 120 mg Vitamin D3 (cholecalciferol) 400 I.U. Vitamin E (dl-alpha-tocopheryl acetate) 30 I.U. Vitamin B1 (thiamine mononitrate) 3 mg Vitamin B2 (riboflavin) 3 mg Niacin (niacinamide) 20 mg Vitamin B6 (pyridoxine hydrochloride) 3 mg Folic Acid 1 mg Vitamin B12 (cyanocobalamin) 8 mcg Calcium (calcium carbonate) 200 mg Iron (carbonyl iron) 29 mg Iodine (potassium iodide) 150 mcg Zinc (zinc oxide) 15 mg
Oxycodone HCl Capsules, CII	Oxycodone hydrochloride 5 mg

Drug Name	Active Ingredients
PreCare Chewables Tablets	Vitamin C (ester C) 50 mg, Vitamin D3 (cholecalciferol) 6 mcg, Vitamin E (dl-alpha-tocopheryl acetate) 3.5 IU, Vitamin B6 (pyridozine hcl) 2 mg, Folic acid USP 1 mg, Calcium (calcium carbonate) 250 mg, Iron (including micromask ferrous fumarate) 40 mg, Magnesium (magnesium oxide) 15 mg, Copper (cupric oxide) 2 mg
PreCare Conceive Tablets	Vitamin C (ester C) 60 mg, Vitamin E (dl-alpha-tocopheryl acetate) 30 IU, Vitamin B1 (thiamin mononitrate) 3 mg, Vitamin B2 (riboflavin) 3.4 mg, Vitamin B3 (niacinamdie) 20 mg, Vitamin B6 (Pyridoxine hcl) 50 mg, Folic Acid 1 mg, Vitamin B12 (cyanocobalamin) 12 mcg, Calcium (as calciPure calcium carbonate) 200 mg, Iron (ferrous fumarate) 30 mg, Magnesium (magnesium oxide) 100 mg, Zinc (zinc oxide) 2 mg, Copper (cupric oxide) 2 mg
PreCare Premier Tablet	Vitamin C (ester C) 50 mg, Vitamin D3 (cholecalciferol) 240 IU, Vitamine E (dl-alpha_tocopheryl acetate) 3.5 IU, Vitamin B1 (thiamine mononitrate USP) 3 mg, Vitamin B2 (riboflavin, USP) 3.4 mg, Vitamin B3 (niacinamide) 20 mg, Vitamin B6 (phridoxine hcl USP) 50 mg, Folic Acid USP 1 mg, Vitamin B12 (cyanocobalamin) 12 mcg, Calcium (calcium carbonate) 250 mg, Iron (elemental iron as sumalate) 30 mg, Magnesium (magnesium oxide, USP) 25 mg, Zinc (zinc oxide USP) 15 mg, Copper (cupric oxide) 2 mg, Docusate sodium 50 mg, Succinic Acid 35 mg.
PremesisRx Tablets	Vitamin B6 (pyridoxine hcl USP) 75 mg, Folic acid USP 1 mg, Vitamin B12 (cyanocobalamin) 12 mcg, Calcium (as CalciPure Calcium carbonate) 200 mg
Prenatal MR 90 FE Tablets	Vitamin A (acetate) 4,000 I.U. Vitamin D (ergocalciferol) 400 I.U. Vitamin E (kl-alpha tocopheryl acetate) 30 I.U. Vitamin C (ascorbic acid and niacinamide ascorbate) 120 mg Calcium carbonate 250 mg Elemental Iron (ferrour fumarate) 90 mg Vitamin B1 (thiamine mononitrate) 3 mg Vitamin B2 (riboflavin) 3.4 mg Niacinamide Ascorbate (pyridoxine HCl) 20 mg Vitamin B6 (pyridoxine HCl) 20 mg Vitamin B12 (cyanocobalamin) 12 mcg Iodine 150 (potassium iodide) mcg Cuppric oxide 2 mg Zinc oxide 25 mg Docusate sodium 50 mg

Drug Name	Active Ingredients
Prenatal Rx 1 Tablets	Prenatal Multivitamin
Prenatal Z, Advanced Formula Tablets	Vitamin A (100% as beta-carotene) 3000 IU, Vitamin C (ascorbic acid) 70 mg, Calcium (calcium carbonate) 200 mg, Iron (ferrous fumarate) 65 mg, Vitamin D3 (cholecalciferol) 400 IU, Vitamin E (kl-alpha tocopheryl acetate) 10 IU, Vitamin B1 (thiamine mononitrate) 1.5 mg, Vitamin B2 (riboflavin) 1.6 mg, Niacin (niacinamde) 17 mg, Vitamin B6 (pyridoxine hcl) 2.2 mg, Folic Acid 1 mg, Vitamin B12 (cyanocobalamin) 2.2 mcg, Iodine (potassium iodide) 175 mcg, Magnesium (magnesium oxide) 100 mg, Zinc (zinc oxide) 15 mg.
PrimaCare Advantage Tablets and Capsules	**AM dose is an oval-shaped, pink, opaque soft gelatin capsule containing the following ingredients:** **Essential Fatty Acids:** Omega-3 Fatty Acids . .. . 650 mg Docosahexaenoic Acid (DHA) .. . 400 mg Eicosapentaenoic Acid (EPA) .. 175 mg α-Linolenic Acid (ALA) . .. 75 mg Linoleic Acid . . . . . 10 mg **Vitamins and Minerals:** Vitamin E (dl-alpha-tocopheryl acetate) . .. .50 IU **PM dose is a dye-free, oval-shaped, pink, film-coated tablet containing the following ingredients:** **Vitamins:** Vitamin C (as *Ester-C®**) . .. . . 100 mg Vitamin D3 (cholecalciferol) . .. . 230 IU Vitamin K . . . . . 90 mcg Vitamin B1 (thiamine mononitrate, USP) .. . . 3 mg Vitamin B2 (riboflavin, USP) .. . . 3.4 mg Vitamin B3 (niacinamide) . . .. . 20 mg Vitamin B6 (pyridoxine hydrochloride, USP) 50 mg Folic Acid, USP 1 mg Vitamin B12 (cyanocobalamin) 12 mcg Biotin 35 mcg Pantothenic Acid 7 mg **Minerals:** Calcium (as CalciPure™ calcium carbonate) 250 mg Iron (elemental iron as Sumalate™†) 30 mg Zinc (zinc oxide, USP) 11 mg Selenium 75 mcg Copper (cupric oxide) 1.3 mg

Drug Name	Active Ingredients
	Chromium 45 mcg Molybdenum 50 mcg **Other:** Docusate Sodium 50mg Succinic Acid 35mg
PrimaCare ONE Capsules –	**Essential Fatty Acids:** shortening, and yellow beeswax. Omega-3 Fatty Acids .. .330 mg Docosahexaenoic Acid (DHA). . .260 mg Eicosapentaenoic Acid (EPA). . . .40 mg á-Linolenic Acid (ALA) . .30 mg Linoleic Acid . .. . .30 mg **Vitamins:** Vitamin C (as Ester-C®*) 25 mg Vitamin D3 (cholecalciferol) 170 IU Vitamin E (dl-alpha-tocopheryl acetate) 30 IU Folic Acid, USP .. . .1 mg Vitamin B6 (pyridoxine hydrochloride) 25 mg Calcium . . . .150 mg Iron: Carbonyl iron (elemental iron). .20 mg SumalateTM† (elemental iron). . . . .7 mg
PrimaCare Tablets and Capsules	AM capsules – Docosahexaenoic Acid DHA 260 mg, Eicosapentaenoic Acid EPA 40 mg, Lenolenic acid (ALA) 30 mg, Linoleic Acid 30mg, Vitamin D3 (cholecalciferol) 170 IU, Vitamin E (dl-alpha-tocopheryl acetate) 30 IU, Calcium (calcium carbonate) 150 mg PM dose – Vitamin C (ester C) 100 mg, Vitamin D3 (cholecalciferol) 230 IU, Vitamin K 90 mcg, Vitamin B1(thiamin mononitrate, USP) 3 mg, Vitamin B2 (riboflavin, USP) 3.4 mg, Vitamin B3 (niacinamide) 20 mg, Vitamin B6 (pyridoxine hcl, USP) 50 mg, Folic Acid 1 mg, Vitamin B12 (cyanocobalamin) 12 mcg, Biotin, Pantothenic Acid 7mg, Calcium (as CalciPure calcium carbonate) 250 mg, Iron (elemental iron as sumalate) 30 mg, Zinc (zinc oxide, USP) 11 mg, Selenium 75 mcg, Copper (cupric oxide) 1.3 mg, Chromium 45mcg, Molybdenum 50 mcg, Docusate Sodium 50 mg, Succinic Acid 35 mg.
Repliva 21/7 Tablets	Sumulate (elemental iron) 70 mg, Ferrous fumarate (elemental iron) 81 mg, Succinic Acid 150 mg, Vitamin C (ascorbic acid) 140 mg, Ascorbic Acid (as calcium ascorbate) 60 mg, Threonic acid (as calcium threonate) 0.8 mg, Folic acid USP 1 mg, Vitamin B12 (cyanocobalamin) 10 mcg

Drug Name	Active Ingredients
* **Pangestyme CN 10 Capsules**	Lipase 10,000 USP Units Protease 37, 500 USP Units Amylase 33,200 USP Units
* **Pangestyme CN 20 Capsules**	Lipase 20,000 USP Units Amylase 75,000 USP Units Protease 66,400 USP Units
* **Pangestyme EC Capsules**	Lipase 4,500 USP Units Protease 25,000 USP Units Amylase 25,000 USP Units
* **Pangestyme MT 16 Capsules**	Lipase 16,000 USP Units Amylase 48,000 USP Units Protease 48,000 USP Units
* **Pangestyme UL 12 Capsules**	Lipase 12,000 USP Units Amylase 39,000 USP Units Protease 39,000 USP Units
* **Pangestyme UL 18 Capsules**	Lipase 18,000 USP Units Amylase 58,500 USP Units Protease 58,500 USP Units
* **Pangestyme UL 20 Capsules**	Lipase 20,000 USP Units Amylase 65,000 USP Units Protease 65,000 USP Units
* **Plaretase 8000 Tablets**	Lipase 8,000 USP Units Amylase 30,000 USP Units Protease 30,000 USP Units

* Defendants' pancreatic insufficiency drugs are subject to the Federal Register Notice of April 28, 2004 (69 FR 23410), in that all exocrine pancreatic insufficiency drugs are new drugs within the meaning of 21 U.S.C. § 321(p), requiring approved new drug applications (NDAs) pursuant to 21 U.S.C. § 355 and 21 C.F.R. Part 314.

Defendants must cease manufacturing and distribution of its all unapproved pancreatic insufficiency drug products if no NDA is submitted on or before April 28, 2009.

Exhibit 4

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	NO. 4:10-CR-
v.	)	
	)	4:10CR00117ERW
ETHEX CORPORATION,	)	
	)	
Defendant.	)	

INFORMATION

THE UNITED STATES ATTORNEY CHARGES:

BACKGROUND

1. At all times relevant to this Information, Defendant ETHEX Corporation ("ETHEX") was a Missouri corporation. ETHEX is a wholly owned subsidiary of KV Pharmaceutical ("KV"), a Delaware corporation which is a publicly traded company. An agent of ETHEX was also a corporate executive at KV. This KV corporate executive will hereafter be referred to as "KV corporate executive A" in this Information. KV corporate executive A is no longer employed at KV.

2. ETHEX and KV operated manufacturing facilities and maintain corporate offices in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri. ETHEX and KV were collectively engaged in the development, manufacture, promotion, sale, and interstate distribution of drugs intended for human consumption. Specifically, within the Eastern District of Missouri and elsewhere, KV manufactured and packaged and ETHEX marketed and shipped into interstate commerce assorted prescription drugs and drugs containing controlled substances in tablet

form, such as morphine sulfate and dextroamphetamine sulfate. Before May 2008, KV had submitted abbreviated new drug applications to the United States Food and Drug Administration ("FDA") for the drugs morphine sulfate, dextroamphetamine sulfate, and propafenone HCl to enable KV to legally manufacture and ETHEX to distribute these prescription drugs.

DRUG TABLET MANUFACTURING PROBLEMS

3. On May 7, 2008, KV and ETHEX received a complaint from a pharmacist at a Walgreen's pharmacy in California reporting the discovery of one oversized morphine sulfate tablet, 60 mg strength, in a 100 count bottle of tablets while the pharmacist was filling a prescription for a customer. According to the pharmacist, the oversized pill weighed over twice the specified amount, but had the same color and engraving as a normal and correctly sized tablet. This pill was manufactured by KV with a "BB2" tablet press in St. Louis County, Missouri and distributed by ETHEX. KV's BB2 tablet press machines had been used by the company for a number of years, and by May 2008 these BB2 machines lacked some of the safety and automation features that more modern tablet press machines typically had. Pursuant to its standard policies and the regulations governing all drug manufacturers, KV immediately began an investigation to determine the root cause of the report of the oversize tablet, trying to decide whether operator error, drug ingredient flow, manufacturing machinery problems, or some combination thereof were creating oversized tablets.

4. On May 8, 2008, KV and ETHEX received a complaint from a Canadian distributor. A Canadian pharmacist reported finding one oversized morphine sulfate tablet, 30 mg strength, that was thicker than a "within specifications" sized 30 mg morphine sulfate tablet from the same tablet bottle. The oversized tablet had the same color and engraving as a normal correctly sized tablet. KV manufactured this tablet with a BB2 tablet press in St. Louis County, Missouri and ETHEX

distributed it. The Canadian distributor estimated that the oversized tablet weighed 65% more than a regular pill, and contained 60% more morphine sulfate than the 30 mg strength listed on the labeling for the drug. KV's root cause investigation was expanded to include this report.

5. As part of KV's root cause investigation, on June 9, 2008 and June 13, 2008, ETHEX and KV issued recalls for specific lots of morphine sulfate, 30 mg and 60 mg strength. The morphine recalls created negative press for KV, and were matters of interest to the Audit Committee for KV's Board of Directors. On June 18, 2008, KV also submitted a field alert to FDA, this time referencing the discovery of oversized morphine tablets in the 30 mg and 60 mg strength during the root cause investigation, but not referencing the discovery of other oversized tablets of other drugs.

6. On June 30, 2008, KV employees discussed the progress of the internal root cause investigation of the two complaints and KV's BB2 tablet press manufacturing processes. During May and June of 2008, as part of the investigation, KV employees had discovered sporadic occurrences of other oversized tablets of drugs and controlled substances beyond morphine sulfate, including propafenone and other drugs. KV's Health Department explored whether any of these oversized tablets of other drugs and controlled substances had potential health risks if such a tablet were consumed. KV's root cause investigation concluded that the root cause of oversized tablets could not be traced to a specific pill press operator or the flow characteristics of an individual drug.

7. One of the prescription drugs that KV manufactured with BB2 machines was called propafenone. Propafenone in the 225 mg strength was one of the drugs where KV had discovered an oversized tablet during its root cause investigation. This tablet was not distributed outside of the manufacturing facility, or packaged or shipped. Propafenone is an anti-arrhythmic drug used to treat some kinds of heart disease. KV's medical assessment for this drug concluded that the ingestion of a single higher-than-expected dose of propafenone had the potential to result in a

significant increase of the drug in individual patients' blood levels, potentially causing hypotension, convulsions, or an increased risk of assorted heart problems.

8. Another prescription drug tablet manufactured by KV with BB2 machines was dextroamphetamine sulfate in the 5 mg strength. Dextroamphetamine sulfate was one of the drugs where KV had discovered an oversized tablet during its root cause investigation after sorting a batch of this drug product on July 2, 2008. This tablet was not distributed outside of the manufacturing facility, or packaged or shipped. KV designed and marketed this drug for use primarily by children, typically ages 3-16. KV's medical assessment concluded that ingestion of an oversized tablet of this drug could create varying results depending on the patient's tolerance and susceptibility to the drug, but adverse effects could include heart problems, hypertension, or tremors.

9. On July 2, 2008, a KV employee presented options for responding to the discovery of oversized tablets of various drugs produced on BB2 machines to KV corporate executive A. One option presented to KV corporate executive A was "to do nothing because the probability of oversized tablets is very very low." KV corporate executive A was advised that other KV employees did not recommend the "do nothing" option because it did not eliminate risk, was not proactive, and would not enhance KV's reputation with FDA. However, over the objections of other employees at KV, KV corporate executive A chose the "do nothing" option, and directed the company not to recall or withdraw from the market any additional drugs. Shortly after KV corporate executive A made the "do nothing" decision, members of the Audit Committee of KV's Board of Directors were alerted to these issues, and retained counsel to conduct an investigation and advise them regarding FDA regulatory matters and compliance issues.

10. During June and July of 2008, KV corporate executive A instructed multiple KV employees to minimize written communications about KV's oversized tablet manufacturing problems, and limit distribution and discussion of any documents discussing these problems given the "business risk" created by these written materials. KV corporate executive A was worried that communicating problems to FDA could lead to FDA insisting on additional recalls, and also wanted to limit the Audit Committee's investigation. KV corporate executive A was concerned about the number of consumer complaints that KV had received after the two morphine sulfate recalls, and thought it was better to leave the drug products "on the market."

11. On July 12, 2008, KV corporate executive A was informed that a patient outside of Missouri complained to KV about the patient's receipt and consumption of crumbly, differently textured, bigger, and thicker than usual morphine tablets manufactured by KV, labeled as 60 mg strength. The patient reported experiencing adverse health effects. This patient was a beneficiary of the Government's Medicare and Medicaid programs, and the Medicare program funded the purchase of these morphine tablets during this time period.

12. On or about September 10, 2008, KV corporate executive A was advised of serious manufacturing issues at KV regarding the manufacturing of morphine sulfate, dextroamphetamine sulfate, and propafenone, as well as the failure to adequately report these issues to FDA.

13. On September 25, 2008, as a result of information developed through their investigation, KV's Audit Committee instructed KV corporate executive A and other KV employees to move quickly and begin discussions with FDA regarding whether additional drug products should be recalled. In response to the Audit Committee's directive, KV employees had discussions and ultimately a meeting with the FDA on October 10, 2008. Afterwards, KV and ETHEX made additional product recalls of assorted drug products on October 15, 2008, November 7, 2008,

November 10, 2008, and December 23, 2008. Effective December 19, 2008, KV and ETHEX voluntarily suspended all shipments of FDA-approved drug products in tablet form, and thereafter implemented a number of remedial improvements to the company's operations. On March 2, 2009, KV entered into a consent decree with FDA to improve and strengthen KV's manufacturing processes.

A DRUG MANUFACTURER'S LEGAL DUTY TO FILE REPORTS WITH FDA

14. The FDA is an agency of the United States government. Under the authority of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-394, FDA regulated the approval, manufacture, and distribution of drug products for human consumption. Under the FDCA, drug manufacturers must generally file a new drug application ("NDA") or abbreviated new drug application ("ANDA") before manufacturing and marketing most drugs in the United States. 21 U.S.C. § 355(a); 21 C.F.R. §§ 314.1 – 314.90, 21 C.F.R. §§ 314.91 – 314.99. The NDA or ANDA contains information about a drug's labeling, conditions of use, and active ingredients, as well as data regarding the chemistry, manufacturing, and manufacturing control methods regarding the drug. 21 U.S.C. § 355(b)(1)(D).

15. Under 21 C.F.R. § 211.188 and 21 C.F.R. § 211.192, drug manufacturers must prepare drug batch production and control records, and have a quality control unit review and approve these records before any drugs are released or distributed. Any unexplained discrepancies or failure of a batch to meet specifications must be thoroughly investigated, whether or not the batch of drugs has already been distributed. Any such investigation shall extend to other batches of the

same drug, or any other drugs that may have been associated with the specific failure or discrepancy, and a written record of the investigation must be made, including any conclusions or follow up.

16. A drug manufacturer must establish and maintain records regarding any significant chemical, physical, or other change in a distributed drug product, or the failure of a drug distributed batch of drugs to meet specifications. 21 C.F.R. § 314.81(b)(1)(ii); 21 U.S.C. § 355(k). If a drug manufacturer has information concerning a significant chemical change in distributed drug products or a failure of a distributed drug batch to meet specifications, it must file a "field alert" with FDA within three working days of receiving such information. 21 C.F.R. § 314.81(b)(1).

17. Under 21 U.S.C. § 331(e), it was unlawful for any person or corporation, with the intent to defraud and mislead, to fail to establish or maintain any record, or make any report required under 21 U.S.C. § 355(k), including records required under 21 C.F.R. § 314.80 and § 314.81.

COUNT ONE

18. The United States incorporates by reference paragraphs 1-17 herein.

19. On or about September 16, 2008, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and elsewhere,

ETHEX CORPORATION

defendant herein, with the intent to defraud and mislead, failed to make a report required under 21 U.S.C. § 355(k). Specifically, the defendant failed to make and submit a field alert report to the U.S. Food and Drug Administration regarding defendant's discovery of oversized tablets of propafenone, 225 mg strength that failed to meet product specifications. All in violation of 21 U.S.C. § 331(e), 21 U.S.C. § 333(a)(2), and 18 U.S.C. § 2.

COUNT TWO

20. The United States incorporates by reference paragraphs 1-17 herein.

21. On or about September 16, 2008, in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and elsewhere,

ETHEX CORPORATION

defendant herein, with the intent to defraud and mislead, failed to make a report required under 21 U.S.C. § 355(k). Specifically, the defendant failed to make and submit a field alert report to the U.S. Food and Drug Administration regarding defendant's discovery of oversized tablets of dextroamphetamine sulfate, 5 mg strength that failed to meet product specifications. All in violation of 21 U.S.C. § 331(e), 21 U.S.C. § 333(a)(2), and 18 U.S.C. § 2.

UNITED STATES OF AMERICA)
EASTERN DIVISION)
EASTERN DISTRICT OF MISSOURI)

I, Andrew J. Lay, Assistant United States Attorney for the Eastern District of Missouri, being duly sworn, do say that the foregoing information is true as I verily believe.

Andrew J. Lay, #28542

Subscribed and sworn to before me this 25th day of February 2010.

CLERK, U.S. DISTRICT COURT

By: DEPUTY CLERK

Exhibit 5

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PUBLIC PENSIONS FUND GROUP, et al.	)	No. 4:08-CV-1859 (CEJ)
Plaintiffs,	)	CLASS ACTION
vs.	)	
KV PHARMACEUTICAL COMPANY, et al.	)	
Defendants.	)	JURY TRIAL DEMANDED

ENGLAND AFFIDAVIT IN SUPPORT OF LEAD PLAINTIFFS' MOTION PURSUANT TO RULE 59(e) AND RULE 60(b)(2) FOR RELIEF FROM THE ORDER OF DISMISSAL TO AMEND THE PLEADINGS PURSUANT TO RULE 15

1. I am Benjamin L. England, Compliance Consultant, with FDAImports.com, LLC and Benjamin L. England & Associates, LLC. I have 17 years experience as a US Food and Drug Administration ("FDA" or the "Agency") official including 4 years as a regulatory microbiologist, 4 years as an investigator and compliance officer, 6 years as a special agent with the Office of Criminal Investigations and 3 years as a regulatory counsel for FDA's Associate Commissioner for Regulatory Affairs. Following my career at the FDA, I have been in private practice as a regulatory consultant and regulatory attorney for 7 years representing manufacturers and distributors of FDA-regulated companies, including pharmaceutical manufacturers. Based upon my experience at FDA, I have performed training for industry representatives and for FDA representatives to include training on FDA enforcement actions, violations, inspections and good manufacturing practices.

2. I have been asked by Labaton Sucharow LLP to evaluate certain documents I have been provided, including various redacted FDA Forms 483, legal briefs and opinions in a matter involving FDA inspections of KV Pharmaceutical Company. I have also been asked to review FDA documents and regulations and federal statutes to evaluate the general and legal significance of items that are included by FDA investigators on FDA Forms 483 at the conclusion of FDA inspections.

3. The following is based upon my evaluation of the documents provided, upon my education, training and experience within the FDA-regulated industry and upon my experience as a former FDA investigator and special agent, FDA compliance officer and FDA regulatory counsel.

4. Under the Federal Food Drug and Cosmetic Act ("FDCA" or the "Act") the FDA possesses the jurisdiction to enter and conduct inspections of pharmaceutical (drug) manufacturing facilities and to view and document the premises where drugs are made and stored, the equipment and processes used to produce drugs, the qualifications, training and conduct of personnel supervising or performing drug manufacturing operations, computer software or systems used to perform, document and report manufacturing functions, and quality control and validation procedures and documentation designed to ensure the drugs manufactured in an inspected facility meet the identity and potency, quality and strength characteristics necessary to ensure drug is safe and effective. 21 U.S.C. § 374. FDA exercises this authority by issuing regulations outlining the good manufacturing practices ("GMP") requirements drug manufacturers must adhere to in order to produce drugs that are not adulterated and therefore in violation of the Act. 21 U.S.C. § 351(a)(2) and 21 CFR Parts 210 and 211. Conduct in a drug

manufacturing facility that falls outside requirements of FDA's GMP regulations amounts to a violation of federal law. 21 U.S.C. § 351(a)(2)

5. FDA's drug inspection program is designed to ensure that drug manufacturers conform to GMPs as required by federal law and federal regulation. Deviations from GMPs represent violations of federal law. 21 U.S.C. § 351(a)(2). Observations made by FDA investigators during a drug inspection equate with observable and documented evidence of a violation of federal law. Congress mandated that FDA provide notice to drug manufacturers at the initiation of a regulatory inspection and at the conclusion of the inspection. 21 U.S.C. § 374(a)(1). The notice issued at the inception of an FDA inspection is to be presented to the owner, operator or agent in charge of the facility, which ordinarily amounts to the most responsible person at the facility when the inspection is initiated. The notice of initiation of an FDA inspection is presented on an FDA Form 482. This requirement is established by federal statute.

6. The purpose of an FDA drug inspection is "to inspect such factory . . . [or] establishment . . . and all pertinent equipment, finished and unfinished materials, containers, and labeling therein." 21 U.S.C. § 374(a)(1). Inspections of factories or establishments where prescription drugs are made "shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing whether prescription drugs . . . are adulterated or misbranded within the meaning of [the] Act, have been or are being manufactured, processed, packed . . . or held in any such place, or otherwise bearing on *violation* of [the] Act." *Id.* (emphasis added).

7. The notice issued at the conclusion of the FDA inspection is also established by federal statute. This concluding notice, the FDA Form 483, must also be presented to the owner,

operator or agent in charge of the inspected facility and it must include the observations of conditions or practices which, in the FDA inspector's judgment, indicate that any drug has been prepared, packed or held under conditions whereby it may have been rendered injurious to health. 21 U.S.C. § 374(b). This notice, therefore, is a written report to the manufacturer's owner, operator or agent in charge providing notice to her or him of observations made by an FDA inspector of manufacturing processes, controls or facilities that are notably deficient with respect to drugs, thereby resulting in an adulteration violation as purposed by Congress in granting inspectional authority to FDA.

8. The FDA Form 483 reinforces, along with FDA's Investigation Operations Manual ("IOM")[1], statutory language indicating that reported observations are not conclusory because they are issued by an FDA inspector and they therefore initially reflect the inspector's judgment (including training and expertise). That is not to say, however, that those observations, when made, are not evidence of violations of federal law and regulation. Rather, the statutory language and FDA policy together enable the Agency to perform additional review of evidence obtained by the FDA inspector so the Agency may, if appropriate, finally qualify or clarify the significance of the observation with respect to drug GMPs. As previously observed, deficiencies in drug GMPs relate in the law to drug safety or efficacy and therefore to adulteration violations. 21 U.S.C. § 351(a)(2). Although FDA inspectors do not cite federal law or regulations (as a matter of policy) on FDA Form 483s, every observation included on such form must relate to a specific federal authority, as elucidated by FDA's IOM. *See* IOM § 5.2.3.2.ff.

9. The fact that FDA procedure requires its inspectors to inform management of an inspected facility that observations of deficiencies recited on a 483 represent the inspector's

[1] The IOM is available at http://www.fda.gov/ICECI/Inspections/IOM/default.htm.

judgment and may be determined to be violations provides FDA with the time to consider other information or evidence when evaluating whether to take regulatory or legal action. *See* IOM § 5.2.7. By contrast, other sections of the IOM instruct the FDA inspector to document observations in a manner that enables the evidence of the observation to be presented in court during litigation as evidence of a violation of federal law and regulation. *See e.g.*, IOM subchapter 5.3 (referencing evidence of insanitary conditions and practices likely to render an article injurious to health or "*otherwise violative*") (emphasis added). Further, FDA inspectors are instructed that the "identification of those responsible for *violations* is a critical part of the inspection, and as important as determining and documenting the *violations* themselves." IOM § 5.3.6. (emphasis added). The IOM also calls on the FDA inspector to exercise judgment when deciding whether to document an individual's responsibility for "violations" observed at the inspected firm by considering such factors as whether such documentation is "required by assignment" or "inspectional findings suggest the possibility of regulatory action" or "background information suggests the possibility of regulatory action." *See id.* Moreover, the IOM explains the importance of determining who in a manufacturing facility is "responsible" to "detect the *violation*", "prevent the *violation*" or "correct the *violation*." *See* IOM § 5.3.6.1. (emphasis added).

10. It is plain that the statutory, regulatory and procedural regimes implemented by FDA fully contemplate that FDA inspectors conducting inspections under the authority of the FDCA are collecting evidence of violations as a matter of law and a matter of course. Moreover, the FDA in its IOM uses the terms "violation" and "observation of deficiencies" (and similar renditions thereof) interchangeably while attempting to retain to itself the ability as a matter of regulatory policy to later qualify or clarify evidence obtained during an inspection.

I declare under penalty of perjury that the foregoing is true and correct. Executed on Mar 18, 2010 in Columbia, Maryland.

Benjamin L. England
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Benjamin L. England & Associates, LLC
6420 Dobbin Road
Suite E
Columbia, MD 21045
410-740-3403

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CURRENT EMPLOYMENT

BENJAMIN L. ENGLAND & ASSOCIATES, LLC
FDAIMPORTS.COM, INC.
March 2008 to Present
Founding Member/Owner – Columbia, MD/Washington, D.C.

Established Food & Drug Consulting Practice and FDA/USDA/Customs and Trade focused law practice representing clients before the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), Bureau of Customs and Border Protection (Customs), and various other federal and state regulatory agencies. Providing counsel and advice related to the manufacture, labeling, marketing, distribution, importation, and exportation of USDA- and FDA-regulated foods, drugs, medical devices, cosmetic products and electronic products.

- Conducts regulatory reviews of and advises related to products, labels, marketing, websites, ingredients, manufacturing and processing regulated by FDA and USDA
- Responses to FDA 483s and Warning Letters and advocates client interests related to product recalls
- Represents clients in Customs civil liquidated damages claims, monetary penalties, and forfeiture actions related to FDA-regulated goods. Represents clients in compliance, enforcement, recalls, and administrative actions brought by FDA, USDA, and Customs.
- Prepares submissions to FDA for dietary supplement companies related to new dietary ingredients and structure or function claims and 510(k)/pre-market notifications for medical devices.
- Assists in reviewing FDA compliance of companies targeted for acquisition by existing firm clients.
- Obtains administrative reversals of adverse agency decisions on scientific, regulatory, administrative, or compliance grounds related to regulated articles.
- Prepares witnesses for congressional hearings or investigations involving legislative, enforcement, or policy matters.
- Co-Chair of Health Industries Committee of the Association of American Exporters and Importers (AAEI) representing interests of branded pharmaceutical and medical device industries before regulatory agencies and development of policy and strategy to advance interests of members importing drugs and devices into the U.S.
- Interprets effect of proposed legislation, regulations, initiatives and guidance on clients' interests.
- Leveraging the trade benefits of membership in Customs' C-TPAT to reduce import delays by other agencies.

PRIOR EMPLOYMENT

JONES WALKER WAECHTER POITEVENT CARRÈRE & DENÈGRE, L.L.P.
-- November 2006 to March 2008--
Special Counsel– Washington, D.C. Office

Established and led Food & Drug Practice counseling clients on FDA and USDA all regulatory matters involving foods, drugs, cosmetics, dietary supplements, medical devices, pharmaceuticals, and electronic products.

RODRIGUEZ O'DONNELL ROSS FUERST GONZALEZ WILLIAMS & ENGLAND, P.C.
-- October 2004 to November 2006 --
Principal – Washington, D.C. and Miami, Florida Offices

Established and led Food & Drug Practice counseling clients on FDA and USDA regulatory matters involving foods, cosmetics, dietary supplements, medical devices, drugs, electronic products.

HOGAN & HARTSON, L.L.P.
– July 2003 to Sept. 2004 –
Associate Attorney – Washington, D.C.

Member Food, Drug and Medical Device Practice Group counseling clients on requirements of FDA and USDA law and regulations as applied to foods, drugs, medical devices, cosmetics, electronic products, and dietary supplements.

U.S. FOOD & DRUG ADMINISTRATION -- 1986 TO 2000

FDA - Regulatory Counsel to the Associate Commissioner for Regulatory Affairs *3/2000 to 7/2003*

Served as Regulatory Counsel to FDA's Associate Commissioner for Regulatory Affairs, addressing import matters, bioterrorism, and product security programs, law, regulation, and policy development, agency-wide implementation of international trade issues for FDA regulated products or jurisdiction, and primary liaison to other federal border agencies. Chaired FDA's Counterfeit Drug Working Group. Co-chair of FDA's Import Strategic Planning Steering Committee to reinvent agency import operations. Developed and conducted training for all field import personnel on FDA law and regulations and application of Customs laws to FDA operations. ORA lead in interrelationships with Customs, USDA, USDOT, and TSA related to safety and security of regulated imported goods. Prepared Commissioner and Associate Commissioners as witnesses for congressional hearings or investigations involving legislative, enforcement, or policy matters. Assisted in agency development, review and clearance of regulatory and administrative programs affecting foods, drugs, and medical devices as well as joint FDA-Customs regulations. Developed expertise in the interrelation of Customs and FDA law, regulations, policy and procedure. Conducted extensive national, international, and broadcast public speaking on FDA's behalf.

Consumer Safety Officer / Compliance Officer *1990 to 1992 and 1998 to 2000*

Applied Federal Food, Drug and Cosmetic Laws and Titles 18 and 19 of the United States Code and directed civil and regulatory investigations related to the fraudulent importation of FDA regulated commodities.

Senior Special Agent, Office of Criminal Investigations *1992 to 1998*

Enforced Food, Drug and Cosmetic Laws, and Title 18. Independently conducted and participated in prosecutions of complex criminal investigations into frauds involving illegal pharmaceutical product diversion, smuggling and fraudulent importation, drug counterfeiting, and financial frauds related to foods, drugs, medical devices, and radiological products, off label promotion of drugs, utilizing traditional and innovative techniques.

Analytical Regulatory Microbiologist *1986 to 1990*

Isolated, enumerated and identified bacterial pathogens from samples of FDA regulated commodities using state of the art laboratory methodologies, technologies, and equipment.

EDUCATION

UNIVERSITY OF MIAMI SCHOOL OF LAW

Juris Doctor conferred December 1999, *summa cum laude*
GPA: 3.892/4.0 Final Class Standing: 2/381 – Dean's List all semesters
Law Review: *University of Miami Law Review*
Order of the Coif

Earned Academic Awards for excellence in: International Business Transactions, U.S. Patent Law, Contracts, International Sales, Business Lawyering, Appellate Advocacy, Moot Court Optional Competition (Best Oral Advocate)

UNIVERSITY OF MARYLAND

Bachelor of Arts, Biological Sciences conferred in 1993, concentration in Microbiology

PROFESSIONAL ASSOCIATIONS

American Bar Association, Florida Bar, Maryland Bar, District of Columbia Bar, Member Association of Food and Drug Officials (AFDO), Member American Association of Exporters and Importers (AAEI)

PUBLICATIONS

Fraud, Freedom & Fundamental Fairness, 53 U. Miami L. Rev. 505, April 1999

Exhibit 6

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PUBLIC PENSION FUND GROUP, Plaintiff, v. KV PHARMACEUTICAL COMPANY, *et al.*, Defendants	Civil Action: 4:08-cv-1859 (CEJ)

AFFIDAVIT OF CANDACE L. PRESTON

STATE OF NEW JERSEY)
) SS.:
COUNTY OF MERCER)

CANDACE L. PRESTON, being duly sworn, deposes and says:

I. Background and Qualifications

1. I have been retained in connection with this matter by Lead Plaintiff's Counsel. In particular, Lead Plaintiff's Counsel requested that I review and discuss whether or not the fact that KV Pharmaceutical Company ("KV" or the "Company") had received numerous Forms FDA-483 (Inspectional Observations) at the conclusion of Food and Drug Administration ("FDA") inspections in 4/2003, 1/2004, 1/2005, 3/2006, 4/2007, 3/2008, 8/2008 and 2/2009 had entered the market prior March 2, 2009, when the FDA filed a Complaint for Permanent Injunction (the "FDA Complaint").

2. I am a founding member of Financial Markets Analysis, LLC ("FMA"). FMA is a securities analysis firm with offices in Princeton, New Jersey, and San Diego, California. FMA provides financial analysis and related consulting to its clients. FMA personnel have frequently been called upon to prepare reports and to testify as securities valuation experts in class actions under Federal and State securities laws. Such testimony has included testifying to matters including: (1) market efficiency; (2) the materiality of information; (3) loss and damage causation; (4) the valuation of publicly traded securities based upon the hypothetical absence of alleged misstatements and the disclosure of alleged omissions and misrepresentations; and (5) damages calculations.

3. I have achieved the professional designation of Chartered Financial Analyst (CFA) and am a member in good standing of the CFA Institute (formerly the Association for Investment Management and Research (AIMR)). The CFA program is a globally recognized standard for measuring the competence and integrity of financial analysts. Its curriculum develops and reinforces a fundamental knowledge of investment principles. The curriculum includes Ethical and Professional Standards, Quantitative Methods, Economics, Financial Statement Analysis, Corporate Finance, Analysis of Debt Investments, Analysis of Equity Investments, Analysis of Derivatives, Analysis of Alternative Investments, Portfolio Management, and Performance Measurement and Attribution. A candidate's ability to apply these principles at a professional level is measured through three levels of examination which must be passed in succession. I participate in the CFA Institute's continuing education program and I am a member of the New York Society of Securities Analysts (NYSSA). A copy of my curriculum vitae is attached as Exhibit A.

4. My opinions and testimony regarding the subject matters listed above have been accepted in numerous United Stated Federal District Court matters. A complete list of matters in which I have testified at deposition or trial within the past four years is attached as Exhibit B.

5. FMA is being compensated in this matter based on the number of hours expended at the rates charged for personnel, which range from $75 to $450 per hour, plus out-of-pocket expenses. My current hourly rate is $450. Neither my, nor FMA's compensation is in any way contingent upon the outcome of this matter.

II. Summary of Opinions

6. Based upon my professional knowledge and experience, as well as my review and analyses of the documents and data listed below, it is my opinion that it was not until the FDA Complaint was filed on March 2, 2009 that the market became aware of the numerous Forms FDA-483 that the company had received as a result of inspections between April 2003 and February 2009.

III. Information Reviewed and Bases for Opinions

7. My opinions are based upon my professional knowledge and experience, as well as my review and analysis of documents and data including the following:

A. The Corrected Consolidated Class Action Complaint;
B. Defendants' Memoranda of Law in Support of their Motions to Dismiss Motions ;
C. Lead Plaintiffs' Omnibus Opposition Brief to Defendants' Motions to Dismiss
D. Memorandum and Order dated February 22, 2010;
E. Forms 10-K, 10-Q, 8-K and other filings made by KV with the Securities and Exchange Commission ("SEC") before, during, and after the Class Period;
F. Press releases issued by KV before, during, and after the Class Period;
G. News articles about KV and its competitors published in the general and

financial press before, during, and after the Class Period;

H. Reports about KV published by securities analysts; and

I. Daily price and volume data for KV's common stock during the relevant time period.

IV. Information Available to the Market

8. Information regarding a company generally comes to the market through a number of different channels including electronic media, print media, and analyst reports. I examined all of these channels to determine if any information regarding the numerous Forms FDA-483 received by KV were discussed, referred to, or otherwise mentioned prior to the filing of the FDA Complaint.

9. I searched the *Dow Jones/Factiva* and *Bloomberg Professional Service* for any information regarding KV for the period April 1, 2003 through February 24, 2009. These data bases carry information from the Wall Street Journal, the New York Times, international, local and regional newspapers, newswires, magazines and industry publications. *Dow Jones/Factiva* had 1966 separate entries for that period of which none mentioned the receipt by the Company of a Form FDA-483. *Bloomberg Professional Service* had 517 entries for the same period and none mentioned KV's receipt of a Form FDA-483.

10. In addition, I searched analyst reports through the *Thomson/Reuters* data base. I found no mention of the numerous Forms FDA-483 that the Company received during the putative Class Period. I did find that beginning on December 24, 2008 there were mentions of "regulatory problems" and the then-current investigation. The transcript of a conference call held by KV on December 23, 2008 reveals that the Company at that point indicated that one other inspection had occurred in the recent past, but as shown below, gave no inkling of the numerous previous inspections and Forms FDA-483 that had been issued.

Q: Elliot Wilbur: Okay. And with respect to any recent communication with the FDA have, in fact, they scheduled or indicated to you that they are looking to perform any inspection activities associated with some of these recent developments some of these recalls?

A: David Van Vliet: The FDA is currently conducting an inspection at KV. We have had very open discussions with them for sometime [sic] now. And so we are working very closely, keeping them advised of our plans and they have a very high regard for Lachman Consultants…

Q: Elliot Wilbur: Okay. Then one last question, can you give us some sense of when exactly did the FDA inspection commence?

A: David Van Vliet: It was quite recently, I don't remember the exact date. But it was very recently that they came in.

Q: Elliot Wilbur: Okay and this is a broad level cGMP inspection or is this something that has resulted directly from the product recalls that we have seen?

A: David Van Vliet: Well, we are not sure exactly. As you know they make periodic visits and they are here and they haven't concluded their investigation yet. So I guess at the end they will tell us more completely what their objectives were of that particular inspection…

Q: Andrea Bici: Oh, yes. Regarding the timing of when the FDA started its investigation, was it before Mr. Hermelin stepped down or resigned or was ousted or after?

A: David Van Vliet: Oh, it was after…

Q: Well, hi, it's Jim Dawson for Dave Buck. Could you give some specifics on the 43 observations during the FDA's last inspection?

A: David Van Vliet: I don't have those with me nor I memorize [sic] at this point in time. So I can't help you with that right now. Mike did you want to respond?

A: Michael Anderson: I don't – obviously don't have access to them.

11. The lack of specificity about the prior FDA inspections and prior Forms FDA-483 are apparent in the following analyst report, which was published on December 24, 2008.

- We view the news that KV voluntarily suspended tablet shipments as an indicator of serious problems at the Company. It is illogical to believe that the Company just wanted to take an opportunity to look at its quality control procedures. KV was not specific on its Observations on its prior 483 Form from the FDA and a current inspection could reveal other Observations that require remediation.

David G. Buck
The Buckingham Research Group

12. However, it was not until January 2009 that speculation regarding the issuance of a Form FDA-483 to KV appeared in the analyst reports I reviewed. This speculation did not include any information about the numerous Forms FDA-483 that were issued during the period April 2003 through December 2008.

13. In addition to these sources of information, KV was required to make filings with the Securities and Exchange Commission ("SEC"). Filings made by KV provided important information to the market regarding its business prospects, financial statements, status of litigation, and other material matters affecting the value of its securities. These filings were available on-line upon submission to the SEC through the EDGAR system.[1]

14. I searched the Edgar data base for all filings between January 1, 2003 and March 10, 2010. I reviewed 187 documents filed with the SEC during that period including Forms 10Q, 10K, 424B1, 424B3, 11K, 8K Proxy statements, correspondence, amendments to those forms and notices of late filings.[2] Of the 187 documents I reviewed, 117 (63%) were Forms 8-K, a Current Report documenting a material event in the Company's business. Out of the total 187 documents, there were only three that included any information about the KV's receipt of a Form FDA-483. Those three were 8-Ks filed on February 26, 2009, April 30, 2009 and July 24, 2009. The most recent Form 10-K or 10-Q filed by the Company was in September 2008 for the period ending June 30, 2008. In summary, despite dozens of filings each year, prior to the December 23, 2008

[1] According to the SEC's web site (http://www.sec.gov/edgar/aboutedgar.htm): EDGAR, the Electronic Data Gathering, Analysis, and Retrieval system, performs automated collection, validation, indexing, acceptance, and forwarding of submissions by companies and others who are required by law to file forms with the U.S. Securities and Exchange Commission (SEC). Its primary purpose is to increase the efficiency and fairness of the securities market for the benefit of investors, corporations, and the economy by accelerating the receipt, acceptance, dissemination, and analysis of time-sensitive corporate information filed with the agency.

[2] I did not review forms related to the reporting of ownership or changes in ownership of KV securities.

disclosure of an FDA inspection, these filings contained no information regarding Forms FDA-483 received by the Company.

V. Conclusion

15. Based on the above , it is my opinion that there is no evidence that any information regarding the numerous Forms FDA-483 received by KV entered the market prior to the filing of the FDA Complaint.

Candace L. Preston, CFA

Sworn to before me this

17th day of March, 2010

Notary Public

Christine M. Baldwin
Notary Public
Mercer County, New Jersey
My Commission Expires July 24, 2013